THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

In re CELL THERAPEUTICS, INC. CLASS ACTION LITIGATION	Master Docket No. C10-414 MJP (consolidated with Nos. C10-480 MJP and C10-559MJP) **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**
This Document Relates To: All Actions	**JURY TRIAL DEMANDED**

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

Plaintiffs Satish Shah, David Gipson, and Xavian L. Draper (collectively, the "CTIC Investor Group" or "Lead Plaintiffs" or "Plaintiffs"), on behalf of themselves and all other persons similarly situated, by and through their undersigned counsel, allege the following:

I. NATURE OF THE ACTION

1. Plaintiffs bring this Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws (the "Complaint") individually and on behalf of all other persons or entities that purchased or otherwise acquired the securities of Cell Therapeutics, Inc. ("CTI" or the "Company") between March 25, 2008 and March 22, 2010, inclusive (the "Class Period"). Such persons and entities, along with Plaintiffs, are collectively referred to herein as the "Class." This complaint seeks to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act") against the Company as well as the following individuals: James A. Bianco, M.D. ("J. Bianco"), the Company's Chief Executive Officer ("CEO") and a member of the Board of Directors; Craig W. Philips ("Philips"), the Company's President; and Louis A. Bianco ("L. Bianco"), the Company's Executive Vice President, Finance and Administration (collectively, the "Individual Defendants" and with the Company, the "Defendants").

II. JURISDICTION AND VENUE

2. This action arises under and pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder by the Securities and Exchange Commission ("SEC"), including Rule 10b-5, 17 C.F.R. § 240.10b-5.

3. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa; and 28 U.S.C. § 1331.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

4. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(c). Many of the acts and transactions that give rise to the violations of law alleged herein, including the dissemination to the public of materially untrue and misleading press releases and filings with the SEC, occurred in, or were initiated from, this District. During the Class Period, CTI maintained its headquarters in this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce.

III. PARTIES

A. Lead Plaintiffs

6. Plaintiff Satish Shah, as set forth in his certification attached hereto, purchased the publicly traded securities of CTI at artificially inflated prices during the Class Period and was damaged when the stock price fell dramatically after the true facts were revealed. A copy of Plaintiff Shah's certification is annexed hereto as Exhibit A.

7. Plaintiff David Gipson, as set forth in his certification attached hereto, purchased the publicly traded securities of CTI at artificially inflated prices during the Class Period and was damaged when the stock price fell dramatically after the true facts were revealed. A copy of Plaintiff Gipson's certification is annexed hereto as Exhibit B.

8. Plaintiff Xavian L. Draper, as set forth in his certification attached hereto, purchased the publicly traded securities of CTI at artificially inflated prices during the Class Period and was damaged when the stock price fell dramatically after the true facts were revealed. A copy of Plaintiff Draper's certification is annexed hereto as Exhibit C.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
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Fax: (206) 343-9636

B. Defendants

9. Defendant CTI is a corporation organized and existing under and by virtue of the laws of the State of Washington. It maintains its principal executive offices at 501 Elliott Avenue West, Suite 400, Seattle, Washington. For all relevant time periods, the Company has been listed on the National Association of Securities Dealers' Automated Quotation ("NASDAQ") exchange under the ticker symbol CTIC.

10. Defendant J. Bianco was, at relevant times, the Company's CEO and a member of CTI's Board of Directors.

11. Defendant L. Bianco was, at relevant times, the Company's Executive Vice President, Finance and Administration.

12. Defendant Philips was, from August 2008 through the end of the Class Period, the Company's President. Mr. Philips provided services to the Company as a consultant from April 2008 until he assumed the position of President.

13. Defendants J. Bianco, L. Bianco, and Philips are collectively referred to as the "Individual Defendants."

IV. CLASS ACTION ALLEGATIONS

14. Plaintiffs bring this action on their own behalf and as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of the Class consisting of all persons or entities who purchased or otherwise acquired CTI stock and warrants during the Class Period. Excluded from the Class are Defendants, members of the Defendants' immediate families, and any person, firm, trust, corporation, officer, director or other individual or entity in which any Defendant has a controlling interest or which is related to or affiliated with any of the

Zwerling, Schachter, & Zwerling, LLP
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Fax: (206) 343-9636

Defendants, and the legal representatives, agents, affiliates, heirs, successors-in-interest or assigns of any such excluded party.

15. The members of the Class are so numerous that joinder of all members is impracticable. As of March 22, 2010, there were approximately 616 million shares of the Company's common stock outstanding. During the Class Period, the Company's common stock was listed and actively traded on the NASDAQ under the symbol "CTIC".

16. The precise number of Class members is unknown to Plaintiffs at this time but is believed to number in the thousands, at a minimum. In addition, the names and addresses of the Class members can be ascertained from the books and records of CTI and/or its transfer agent. Moreover, notice can be provided to such record owners by a combination of published notice and first-class mail using techniques and a form of notice similar to those customarily used in class actions arising under the federal securities laws.

17. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class. Plaintiffs have retained competent counsel highly experienced in class action litigation under the federal securities laws to further ensure such protection, and intend to prosecute this action vigorously.

18. Plaintiffs' claims are typical of the claims of the other members of the Class because Plaintiffs' and all the Class members' damages arise from and were caused by the same materially false and misleading representations and omissions made by or chargeable to Defendants. Plaintiffs do not have any interests antagonistic to, or in conflict with, the Class.

19. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Since the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible

Zwerling, Schachter, & Zwerling, LLP
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Fax: (206) 343-9636

for the Class members to seek redress for the wrongful conduct alleged. Plaintiffs are not aware of any difficulty in the management of this litigation which would preclude its maintenance as a class action.

20. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

b) Whether Defendants' statements during the Class Period omitted and/or misrepresented material facts about, among other things, CTI and its business and financial condition, performance, prospects, operations and management of the Company; and

c) The extent of damages sustained by members of the Class and the appropriate measure of such damages.

21. Plaintiffs rely, in part, on the fraud-on-the-market doctrine. At all relevant times, the market for CTI stock was an efficient market for the following reasons, among others:

a) CTI stock met the requirements for listing, and was listed and actively traded, on the NASDAQ, a highly efficient market.

b) As a regulated issuer, CTI filed periodic public reports with the SEC and the NASDAQ.

c) CTI stock was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain

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customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

d) CTI regularly issued press releases that were carried by national newswires. Each of these releases was publicly available and entered the public marketplace.

22. As a result, the market for CTI securities promptly digested current information with respect to the Company from all publicly-available sources and reflected such information in CTI's stock price.

V. PLAINTIFFS' INVESTIGATION AND CONFIDENTIAL SOURCES

23. Plaintiffs' allegations are based upon their counsel's investigation, which included, among other things: (a) review and analysis of public filings made by the Company and other related parties and non-parties with the SEC; (b) review and analysis of press releases and other publications disseminated by Defendants and other related non-parties; (c) review and analysis of news articles and shareholder communications; and (d) review and analysis of other publicly available information concerning Defendants and related nonparties.

24. Plaintiffs' allegations are also based upon information provided by former employees of CTI with knowledge of the Company's practices, including, but not limited to, the following confidential witnesses:

1) Confidential Witness 1 ("CW1") is a former Vice President of Clinical Development and Regulatory Affairs at CTI and worked at CTI from November 2007 to March 2009. CW1's responsibilities included being the primary point of contact for communications with the United States Food & Drug Administration ("FDA"). CW1 reported directly to Defendants J. Bianco and L. Bianco.

2) Confidential Witness 2 ("CW2") is a former Executive Assistant to two of CTI's Vice Presidents of Clinical Development and Regulatory Affairs

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and worked at CTI from January 2006 to December 2008. CW2's responsibilities included the final preparation of all communications with the FDA and required CW2 to know the details of each clinical trial. During CW2's employment, CW2 routinely communicated with other employees working at CTI's corporate headquarters in Seattle. CW2's specific daily duties included posting information about the clinical trials to the http://www.clinicaltrials.gov website as well as the FDA website. In satisfaction of these duties, CW2 would ask coworkers questions and post the information in their answers to the websites.

3) Confidential Witness 3 ("CW3") is a former Administrator in the Quality Department at CTI and worked at CTI from before the Class Period began through after the Class Period ended.

4) Confidential Witness 4 ("CW4") is a former Manager in the Corporate Communications Department at CTI and worked at CTI from before the Class Period began through after the Class Period ended. CW4 reported directly to Daniel G. Eramian, the Executive Vice President of CTI's Corporate Communications Department throughout the Class Period.

5) Confidential Witness ("CW5") is a former Assistant Controller at CTI and worked at CTI from before the Class Period began through after the Class Period ended. CW5's supervisors at CTI reported to Defendant L. Bianco.

VI. FACTUAL BACKGROUND

A. CTI's Business and Operations

25. CTI is a biopharmaceutical company that seeks to develop and commercialize novel agents that are intended to improve the safety and efficacy of existing standard-of-care chemotherapies as well as those that have new or unique mechanisms to kill cancer cells.

26. As a pharmaceutical developer, CTI has obligations to ensure that the drug products it sells meet federal efficacy and safety standards. The FDA process of gaining approval is long and expensive. It takes on average 12 years and over $700 million to get a new drug from molecule to market. Once a company develops a drug, it generally undergoes years of laboratory testing before an application is made to the FDA to begin testing the drug in human beings. Only one in 1,000 of the compounds that enter laboratory testing will ever reach

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human testing. Only 8% of drugs that enter phase I clinical trials are eventually approved by the FDA.

27. As a way to streamline some of this process, the FDA developed an expedited process of drug testing and approval called the Special Protocol Assessment ("SPA"). An SPA is an agreement between the FDA and an entity conducting a phase III clinical trial (the "sponsor") establishing the trial's design, clinical endpoints, and statistical analyses. The SPA is essentially a pre-approval commitment from the FDA stating the drug will be approved if: (i) the sponsor completes the study as proposed; and (ii) the drug shows efficacy. According to the FDA, once the proposed design, execution, and analysis of an SPA are agreed upon, the FDA will not alter its perspective on these issues unless public health concerns come to light. Failure of a sponsor to follow the agreed-upon protocol will be interpreted by the FDA as the sponsor's understanding that the SPA is no longer binding. ***An SPA can only be modified if the sponsor and the FDA agrees in writing to modifications that would improve the study.*** *See* Guidance for Industry: Special Protocol Assessment, FDA, page 9 (May 2002) ("A documented special protocol assessment can be modified if (1) FDA and the sponsor agree in writing to modify the protocol (section [505(b)(5)(C)] of [the Federal Food, Drug, and Cosmetic Act]), and (2) such modification is intended to improve the study. A special protocol assessment modified in this manner will be considered binding on the review division . . . .").

28. Although many communications between the FDA and sponsoring institutions are a matter of public record, communications regarding SPA agreements are kept confidential by the FDA. ***Therefore, the only means by which the market learns of an SPA agreement is through public statements by the sponsor.*** The FDA is under no obligation to inform the market of the existence, alteration, or cancellation of an SPA.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
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29. The value of an SPA to the sponsoring institution cannot be underestimated. It is an assurance to both the sponsoring company and its investors that if the clinical trial is performed as planned, with the expected results, the drug will be approved.

B. CTI's Obligations Under the Securities Laws

30. As a publicly traded company, CTI had obligations under the federal securities laws. Generally, CTI had a duty to disclose the true financial condition and known trends and uncertainties of its business to the public by way of public disclosures through filings with the SEC. In addition, 17 C.F.R. § 229.303(a) ("Section 303"), a duly-adopted SEC regulation, required the Company in its Form 10-Ks and 10-Qs to: "provide information as specified in paragraphs (a) (1), (2) and (3) with respect to liquidity, capital resources and results of operations and also shall provide such other information that the registrant believes to be necessary to an understanding of its financial condition, changes in financial condition and results of operations."

31. Further, sub-section (a)(3)(ii) of Section 303 required CTI, in each of its quarterly and annual reports, to "(ii) Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed."

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C. CTI Purchases Pixantrone, a Potential Blockbuster Anti-Tumor Agent, and Commences a Phase III Trial ("EXTEND" or "PIX301")

32. As part of its strategy for pursuing new cancer drugs, CTI purchased Pixantrone, an anti-tumor agent, from Novuspharma in 2003. Pixantrone is a novel aza-anthracenedione compound related to anthracyclines and anthracenediones such as doxorubicin and mitoxantrone. This is a class of drugs whose anti-cancer activity is linked to inhibition of cell division and DNA adduct formation. While effective, this class of anti-cancer agents is associated with significant cardiac toxicity and therefore the lifetime dosage limits of these drugs must be limited. Unlike other anthracycline-like agents, Pixantrone is unable to bind iron and therefore does not form the harmful free-radicals thought to be the cause of cardiac toxicity seen with other drugs in this class. CTI hoped that Pixantrone would be a safer alternative to the traditional anthracycline drugs.

33. CTI began testing Pixantrone as a treatment for Non-Hodgkins Lymphoma ("NHL"). NHL is the 6th most common type of cancer, with an incidence of 66,000 patients annually in the United States. Aggressive NHL comprises 60% of all NHL. Without intensive chemotherapy, survival for patients with aggressive NHL is short. Had Pixantrone lived up to its expectations, it would have been a blockbuster drug for CTI (*i.e.*, a pharmaceutical product that generates over a billion dollars a year in sales).

34. As part of its development of Pixantrone, CTI developed a Phase III trial for aggressive NHL called the EXTEND or PIX301 trial. EXTEND was designed as a single-agent treatment as salvage regimen in patients with relapsed aggressive NHL who have failed standard induction chemotherapy and at least one other combination chemotherapy regimen. Randomized patients would get either Pixantrone or another single-agent drug, of the

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physician's choice, used for the treatment of this patient population. The trial was designed for 320 enrollees.

35. On March 4, 2004, CTI announced that the FDA had "provided guidance" through the SPA for the EXTEND trial. CTI never publicly disclosed the terms of the SPA.

36. In July 2004, the FDA granted fast track designation for Pixantrone for the potential treatment of relapsed aggressive NHL on the basis that relapsed aggressive NHL in the third-line or sub-segment recurrence is a life threatening disease and responses have been noted in phase II trials with patients with relapsed, aggressive NHL. Distinct from the SPA process, the FDA Fast Track Development Program is a designation of the FDA that accelerates the approval of investigational new drugs undergoing clinical trials. Such status is often given to agents that show promise in treating serious, life-threatening medical conditions for which no other drug either exists or works as well. A drug that receives Fast Track designation is eligible for some or all of the following: more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials; eligibility for FDA Accelerated Approval, i.e., approval on an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit; and Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed (NDA review usually does not begin until the drug company has submitted the entire application to the FDA).

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D. CTI's Slow Patient Enrollment and Dire Financial Situation Lead It to Violate the SPA

37. Because of the trial's design, CTI had difficulty recruiting the number of patients needed to comply with the terms of the SPA. By the middle of 2007, after nearly three years of attempting to enroll patients, CTI had only managed a fraction of the number of patients needed to satisfy the original trial design, which called for 320 patients in the study.

38. In July 2007, CTI and the FDA discussed the possibility of ending the EXTEND trial early with fewer patients than planned. On August 9, 2007, CTI announced that it "plan[ned] to meet with the FDA to discuss using data from the EXTEND and RAPID clinical trials to expedite submission of an NDA relating to Pixantrone." On September 6, 2008, CTI announced that it received "guidance" from the FDA "that a primary endpoint analysis of less than the initially-projected 320 eligible patients could be acceptable for NDA submission if it is able to demonstrate a statistical significant difference between treatment arms." In addition, CTI announced that the FDA agreed that randomized safety data from RAPID, a phase II study of Pixantrone that had reported positive interim analysis results in July 2007, "could be used to support the EXTEND results in an NDA submission for Pixantrone."

39. In addition, towards the end of 2007 and at the beginning of 2008, CTI was in the midst of substantial financial difficulties and faced the prospect of being unable to afford to continue the steps needed to obtain FDA approval of Pixantrone, particularly in light of the slow rate of enrollment in EXTEND which had not improved. CW5 reported that the Company always "slow paid" its vendors. CW5 said that, throughout CW5's employment, if the terms of the agreement with a vendor were to make payments within 30 days, CTI would not pay until 6 months had elapsed. CW5 further stated that for the last half of 2007 and the first half of 2008,

Zwerling, Schachter, & Zwerling, LLP
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the financial constraints at the Company became particularly severe because the Company was out of money and it took CW5 much longer to pay bills. Indeed, CW1 reported that in December 2007 CTI stopped paying its vendors, including the Outside Contract Researchers hired to perform the Pixantrone studies.

40. Because of these financial pressures, and in a desperate effort to accelerate the FDA approval process and reduce its cost, CTI decided to shortcut the EXTEND trial and close the study without the full number of patients required by the trial design. CW2 stated that the reason the company closed enrollment in EXTEND was because the Company had run out of money.

41. On March 25, 2008, CTI announced that it had closed enrollment in the EXTEND trial with 140 patients – 44% of the number originally agreed upon with the FDA under the SPA. As revealed only at the end of the Class Period by the FDA, CTI made the decision to close the trial early without having any formal discussions with the FDA. Thus, this fact was not disclosed to the public during the Class Period. Defendants knew, however, that because closing the trial without enrolling sufficient patients was a material deviation from the terms of the SPA, the SPA ceased to be binding on the FDA. In other words, even if the drug showed efficacy and safety among the 140 patients enrolled, the FDA could still deny approval.

42. Indeed, Defendants were well aware that the SPA was no longer binding. According to CW1, the SPA process was well known in the pharmaceutical industry: a sponsor submits the protocol, but if it makes any changes, then the SPA, for all intents and purposes, does not exist and provides no benefit. The Company's Form 10-K filings consistently contain language describing the SPA process and acknowledging that, except in limited circumstances, SPA agreements may not be changed after the clinical studies begin without voiding the SPA.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

43. In fact, in March 2008, when the enrollment number was reduced, CW1 personally met with defendants J. Bianco and L. Bianco and made sure that they understood that because the protocol had been changed, the SPA was no longer active. CW1 stated that both defendants J. Bianco and L. Bianco were aware that the EXTEND trial was thereafter proceeding without the SPA. CW3 confirmed that "everyone" knew that the SPA must be followed or the FDA would reject the SPA.

44. Even with the reduction in operating costs due to the closing of the EXTEND study earlier than necessary to enroll the full 320 patients called for in the trial design, Defendants still needed to raise substantial operating capital in order for the Company to continue operating. If the public became aware of loss of the SPA, these efforts would become, as s practical matter, economic unfeasible. As a result, Defendants engaged in a repeated pattern of misleading the shareholders and investing public into believing the SPA was still valid and that the Company would soon file an NDA under the SPA based on the promising data coming out of the EXTEND study. In fact, without the SPA, the chances of FDA approval of Pixantrone were substantially diminished and, if public investors knew that CTI had invalidated its SPA, shares of CTI securities would have immediately collapse and new infusions of cash would have been virtually impossible to obtain. In turn, the Company would have faced a fiscal crisis that would, under the conditions at the time, likely forced it into bankruptcy.

E. Defendants Mislead Shareholders and the Investing Public into Believing the SPA Was Still Valid

45. At the time Defendants closed enrollment in EXTEND in violation of the SPA, Defendants had an obligation to disclose to the market that the SPA was lost. Defendants failed to do so. Rather than disclose to the public that Pixantrone's approval was now much less

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

certain, Defendants made public statements designed to mislead the public into believing the SPA was still valid and would benefit the Company. Further, in SEC filings, press releases, earnings calls, and other public statements, Defendants knowingly or recklessly failed to disclose the material increase in the risk that Pixantrone would not be granted approval because EXTEND was no longer being conducted under the SPA.

46. In press releases and other public statements, Defendants continued to remind investors that the EXTEND trial had been granted an SPA, despite the fact that the SPA was no longer valid. Because Defendants continued to refer to the EXTEND SPA in their public statements and because Defendants failed to disclose that the Company's significant deviation from the terms of the SPA was not made pursuant to a formal agreement with the FDA, coupled with the Company's public statements regarding its meeting with the FDA to expedite the approval of Pixantrone, investors and analysts continued to believe that the SPA was still valid, despite the Company's deviation from the trial design.

47. Despite Defendants' affirmative duty – throughout the Class Period – to disclose both present facts and "known trends or uncertainties" that could have a material impact on CTI's revenue or income, in particular the significantly diminished prospect for Pixantrone's approval, CTI's filings with the SEC contained no indication that the SPA was no longer valid – a fact that Defendants knew or should have known but for their recklessness would have a material adverse impact on CTI's overall financial condition and operations, including, but not limited to, its revenues, net income, and profits. Moreover, the investing public was aware that CTI was required to disclose known risks and uncertainties in its SEC filings. Because there was no discussion of the loss of the benefit created by the SPA in CTI's 10-Ks, 10-Qs, and other public statements, investors and analysts reasonably assumed that the SPA remained in effect.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
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F. Defendants Keep Their Corporate Communications Employees in the Dark

48. Defendants obfuscation of the true state of the EXTEND trial's SPA did not stop with the investing public. Defendants also kept CTI's corporate communication department in the dark. Despite the fact that the loss of the benefit of the SPA was well-known to Defendants J. Bianco and L. Bianco, this information was never communicated to the Communications Department at CTI, the very department tasked with informing the public of major developments at CTI. CW4, an employee in the Communications Department of CTI, stated that "I didn't know that SPA was not in force" and that "I was shocked [when, in February 2010, FDA briefing documents revealed that that CTI had violated the SPA in March 2008]." By keeping non-executive employees in the communications department from becoming aware of the loss of the SPA, Defendants further reduced the possibility that outsiders would learn the truth that the SPA was no longer valid.

G. The Study Continues

49. In August 2008, CTI completed data collection for the primary outcome measurements in the study – the data points that would determine whether the study was a success or not. In November 2008, Defendants finished their analyses of that data and issued a press release on November 11, 2008, announcing the results of the study. Although the press release indicated that the data from the study was positive, CW2 stated that people in the Clinical Development and Regulatory Department as well as Dr. Jack Singer, Medical Director of CTI, were concerned about the quality of the data that came out of the EXTEND trial because it was not hitting the marks it was supposed to and the Company was not getting what it needed from the study. CW2 stated that "[the Company] manipulated data" and that "[the Company] would try to make the data look the way they wanted it to look."

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
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50. On April 13, 2009, CTI began submission of a rolling NDA for Pixantrone to the FDA. According to analysts' comments at the time, analysts believed that the SPA was still in effect and continued to be an important factor in investors' decision to invest in CTI. For example, on May 17, 2009, Iguanabio.com published an analysis of Pixantrone, which concluded that: "In our opinion, the SPA is what is key to approval."

51. On August 24, 2009, CTI issued a press release announcing that the FDA had accepted and filed for review CTI's NDA for Pixantrone. On December 17, 2009, CTI issued a press release announcing that the FDA's Oncologic Drugs Advisory Committee ("ODAC") would review the Pixantrone NDA on February 10, 2010.

H. The Truth Emerges

52. The truth about the EXTEND SPA became public in February and March of 2010. On February 8, 2010, the FDA posted its analysis of Study PIX-301 online in anticipation of a meeting of the FDA's Oncologic Drugs Advisory Committee Meeting ("ODAC") to consider the Company's application for Pixantrone. That report disclosed for the first time that the SPA for Pixantrone had, contrary to the false impression fostered by Defendants' statements, been invalid since March 2008. As the briefing document indicated, the FDA considered the close of enrollment in the EXTEND trial to constitute a breach of the terms of the SPA, rendering the agreement invalid at that time.

53. As a result of these disclosures, on February 8, 2010, the price of CTI's publicly traded common stock dropped approximately 40 percent in one trading day on extremely high and unusual volume. This decrease represented a portion of the artificial inflation, caused by Defendants' false and misleading statements and omissions, being removed from the price of the Company's securities.

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54. When the truth came to light, investors were furious. As one commentator asked, "How is Cell Therapeutics going to explain why it lied about having an SPA for the Pixantrone study?" In response, the Company issued a press release on February 9, 2010, saying that "[the Company] believe[s] that many of the key issues [the FDA] identified are addressed in our own briefing material which is now publically available as well." As a result of these statements, the decline in the price of CTI securities ceased, and the price recovered slightly.

55. Due to inclement weather on February 10, 2010, the ODAC meeting was rescheduled for March 22, 2010. At the rescheduled ODAC meeting, the FDA provided additional details regarding Defendants' violation of the terms of the SPA. Dr. Waxman, the FDA's representative at the meeting, revealed for the first time that, not only did CTI violate the SPA by closing the study enrollment with only 140 patients, CTI did not seek formal guidance from the FDA prior to making its decision to close the trial.

56. Later during that meeting, the ODAC panel voted unanimously that CTI's clinical trial data was not adequate to support the approval of Pixantrone. CW1 stated that, based on the information that was presented at the ODAC, CW1 was not surprised that Pixantrone was not approved. Thus, Defendants' undisclosed gamble on the combination of data from the RAPID and EXTEND studies to provide the support for the Pixantrone NDA, notwithstanding that Defendants conducted the EXTEND study in violation of the SPA and, therefore, would not benefit from it, utterly failed. In response, CTI's stock fell approximately 48 percent in one day's trading of over 116 million shares.

57. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

VII. OMMISSIONS AND MISSTATEMENTS

A. Defendants' Pre-Class Period Statements and Omissions "Set the Scene"

i. CTI Announces That the EXTEND Trial Has Received an SPA

a) March 4, 2004 Press Release

58. On March 4, 2004, CTI issued a press release entitled "Cell Therapeutics, Inc. to Initiate Pivotal Trial for Pixantrone: First Randomized Controlled Trial Using FDA Special Protocol Assessment (SPA) Procedure Will Target Potential Market of 30,000 NHL Patients in the U.S." The press release stated, in relevant part:

> ***Cell Therapeutics, Inc. . . . announced that the U.S. Food and Drug Administration has provided guidance through the Special Protocol Assessment (SPA) process for a randomized pivotal trial of Pixantrone in the treatment of relapsed, aggressive non-Hodgkin's lymphoma (NHL). The trial protocol and supporting data are in the final stages of review with the FDA and initiation of the pivotal study is planned for later this month.*** The trial is designed to examine the complete response (CR) rate, time to tumor progression, and overall survival of patients with aggressive NHL who have failed front-line and at least one second-line multi-agent chemotherapy regimen. Patients will be randomized to receive either Pixantrone or another currently used, single-agent drug of physician's choice. ***FDA has indicated that Pixantrone would qualify for accelerated approval based upon the successful conclusion of this trial and supporting data from ongoing and completed clinical studies. The trial is expected to enroll approximately 320 patients with enrollment taking approximately 12 months to complete.***

[Emphasis added]

59. The press release also provided the following description of the SPA process:

> The special protocol assessment process provides a forum for FDA and the sponsor to reach agreement as to the design, execution, and analyses proposed in protocols reviewed under this process. ***In general, these assessments are considered binding on the review division as well as the sponsor, unless public health concerns unrecognized at the time of a protocol assessment become evident or other scientific concerns arise.***

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

b) CTI's 2003 Form 10-K, Filed March 12, 2004

60. On March 12, 2004, CTI filed its Form 10-K for 2003, ending December 31, 2003. The 10-K reported on the acquisition and development of Pixantrone, stating, at p. 40:

> We acquired pixantrone, a novel anthracycline, for the treatment of NHL, through our merger with Novuspharama S.p.A. in January 2004. We are developing pixantrone, and plan to initiate a pivotal phase III trial in relapsed aggressive NHL in the first half of 2004.

This "pivotal phase III trial in relapsed aggressive NHL" would become known as the PIX301 or EXTEND study.

61. The 2003 10-K also laid out the Company's overall strategy for Pixantrone trials, generally, and the "pivotal phase III trial", specifically, stating, at p. 14:

> We are currently conducting or plan to conduct one phase III trial, three phase II trials, one phase II/III trial in indolent NHL and two phase I trials. The trial in indolent NHL has been modified and reduced to a registration supporting study based on our strategy to conduct a pivotal phase III trial in aggressive NHL, which we believe provides the fastest route to registration for Pixantrone. ***We intend to begin a randomized pivotal phase III trial for relapsed, aggressive NHL during the first half of 2004. We expect to have data from the pivotal trial and, if the trial is successful, we intend to file an NDA for pixantrone in late 2005 or early 2006.*** We believe pixantrone complements our hematology and oncology expertise and our growing TRISENOX commercial franchise.
>
> * * *
>
> Recently, we met with the FDA and discussed the design for a pivotal clinical trial of single-agent pixantrone in the treatment of third-line relapsed aggressive NHL. ***A SPA package was filed and we expect to initiate a pivotal trial of pixantrone for relapsed NHL in approximately 320 patients in the first half of 2004.*** We believe such a trial would qualify for accelerated review and approval under current FDA guidelines. Enrollment is expected to take approximately one year and assuming a positive outcome for this trial we would intend to file an NDA in late 2005 or early 2006.

[Emphasis added]

62. The 2003 10-K also provided the following description of the SPA process, at page 20:

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> The FDCA permits FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as Special Protocol Assessment, or SPA. ***These agreements may not be changed after the clinical studies begin, except in limited circumstances.***

[Emphasis added]

c) August 8, 2006 Press Release

63. On August 8, 2006, CTI issued a press release entitled "Cell Therapeutics, Inc. (CTI) Announces Encouraging Pixantrone Phase III Interim Data; Independent Data Monitoring Committee Recommends Study Continue." The press release stated that:

> The EXTEND clinical trial is a phase III trial for patients with relapsed, aggressive non-Hodgkin's lymphoma who have received two or more prior therapies. The trial is being conducted in 130 sites in 17 countries. Patients are randomized to receive either pixantrone or another single-agent drug of physician's choice currently used for the treatment of this patient population. The trial is designed to examine the complete response (CR) or unconfirmed complete response (uCR) rate, time to tumor progression, and overall survival. The study was powered based on a CR rate assumption of less than 5 percent for the control arm and a 10 percent improvement in CR rate for the pixantrone arm. ***The study is being conducted under a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA) and pixantrone has received fast track designation for this indication.***

[Emphasis added]

d) CTI's 2006 Form 10-K, Filed March 16, 2007

64. On March 16, 2007, CTI filed its 2006 Form 10-K for the period ended December 31, 2006. The form reported on the EXTEND trial, stating at page 7:

> We have several clinical trials ongoing, including a pivotal phase III trial for the treatment of patients with relapsed aggressive NHL, a condition for which there are no chemotherapy drugs approved in the United States. ***This 320 patient study is an international, randomized trial comparing pixantrone to a single agent of the treating physician's choice. The primary endpoint of the study is complete response rate. We are currently enrolling patients on this clinical trial.*** An interim analysis of CTI's ongoing phase III study of pixantrone, known as the EXTEND study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study will continue.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> Another interim analysis of the study will be performed on approximately 100 patients and is targeted for the second half of 2007.
>
> * * *
>
> In July 2004, we announced that the FDA granted fast track designation for Pixantrone for the treatment of relapsed aggressive NHL.

[Emphasis added]

65. The 2006 10-K also provided the following description of the SPA process, at page 14:

> The FDCA permits the FDA and IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as special protocol assessment, or SPA. ***These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of an SPA, however, does not assure approval of a product candidate.***

[Emphasis added]

ii. Defendants Start Looking for Ways to Accelerate the Submission of the Pixantrone NDA

a) CTI's Form 10-Q for 2Q 2007, Filed August 9, 2007

66. On August 9, 2007, CTI filed its 10-Q for the second quarter ended June 30, 2007. This 10-Q reported on the EXTEND trial, stating at page 18:

> An interim analysis of our ongoing phase III study of pixantrone, known as the EXTEND or PIX 301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study will continue. Pixantrone is also being studied in a phase II/III study, known as RAPID or PIX203 . . . . An interim analysis of the RAPID study was reported in July 2007. The interim analysis of the study showed that to date a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). . . . The study, which is targeting enrollment of 280 patients, is expected to complete enrollment in 2009. ***We plan to meet with the FDA to discuss using data from the EXTEND (PIX301) and RAPID (PIX203) clinical trials to expedite submission of an NDA related to pixantrone.***

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

b) September 6, 2007 Press Release

67. On September 6, 2007, CTI issued a press release entitled "Discussions With FDA on Pixantrone EXTEND (PIX301) Trial Provide Path for NDA Submission; Significant Difference in Primary Endpoint Could be Acceptable With Fewer Patients Than Originally Planned." The press release announced that:

> [F]ollowing discussions with the U.S. Food and Drug Administration (FDA) regarding its EXTEND (PIX301) trial for patients with aggressive non-Hodgkin's lymphoma (NHL) the Company has decided to conduct a full analysis of the trial instead of an interim analysis as previously planned. ***The decision was based in part on the Agency's guidance that a primary endpoint analysis of less than the initially-projected 320 eligible patients could be acceptable for New Drug Application (NDA) submission if it is able to demonstrate a statistically significant (p<=0.05) difference between treatment arms. In addition, the FDA agreed that randomized safety data from the RAPID (PIX203) study (CHOP-R vs. CPOP-R) could be used to support the EXTEND results in an NDA submission for pixantrone. Based on this guidance the Company currently anticipates completing enrollment in the EXTEND trial in the fourth quarter of this year with primary endpoint data and final results being reported in the first half of 2008.*** Pixantrone has received fast track status from the FDA for this indication.
>
> ***"This was a very important outcome for CTI and the PIX301 trial timeline. If we achieve the primary endpoint of the study, even with fewer than 320 patients, we could submit our NDA," said James A. Bianco, M.D., President and CEO of CTI.*** "Going straight to a final analysis will allow us the potential to submit an NDA for pixantrone and receive approval in 2009. The inclusion of safety data from the randomized trial of pixantrone versus doxorubicin is also a very important recognition of the potential toxicity benefit of this novel agent."

[Emphasis added]

68. These statements were designed to give the impression that CTI had reached an agreement with the FDA that would allow CTI to continue to rely on the SPA when it ultimately submitted an NDA, despite conducting the study with fewer patients than originally planned. The statements were also designed to conceal the very material invalidation of and loss of benefit to the Company from the SPA because the FDA had not agreed to the reduction in the

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

number of participants in the EXTEND trial. Without the agreement of the FDA, such deviation from the SPA voided it and materially increased the risk that Pixantrone would not receive FDA approval.

69. In the same press release, Defendants again highlight that the EXTEND trial was granted an SPA by the FDA:

> The EXTEND clinical trial is a phase III single agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who have received two or more prior therapies and who are sensitive to treatment with anthracyclines. The trial is being conducted at 130 sites in 17 countries. Patients are randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician. The trial is designed to examine the complete response (CR) or unconfirmed complete response (uCR) rate, time to tumor progression, and overall survival. The study was powered based on a CR rate assumption of less than 5 percent for the control arm and a 10 percent improvement in CR rate for the pixantrone arm. ***The study initially anticipated the requirement of 320 patients to meet the statistical assumptions of the trial. The study is being conducted under a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA) and pixantrone has received fast track designation for this indication.***

[Emphasis added]

70. These statements imply that CTI was still conducting EXTEND under the SPA when, in fact, the FDA had not agreed to the variations from the SPA. The SPA was not valid if CTI did not obtain approval to reduce enrollment in the trial. Thus, the inclusion of the phrase "initially anticipated" was included to mislead investors to believe something had changed that would allow CTI to reduce the size of the study and still retain the SPA. In fact, nothing had changed from when the FDA "initially" required 320 patients for EXTEND to satisfy the terms of the SPA, and any reduction in the number of patients would void the SPA.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

B. Defendants' Materially False and Misleading Statements and Omissions During the Class Period

i. March 25, 2008 Press Release

71. On March 25, 2008, the first day of the Class Period, CTI issued a press release entitled "Cell Therapeutics, Inc. (CTI) Announces Enrollment Complete in Phase III Extend (PIX301) Clinical Trial of Pixantrone in Patients With Second or Greater Relapse of Diffuse Large B Cell NHL." With regard to the status of the EXTEND study, the press release stated:

> Cell Therapeutics, Inc. . . . announced today that enrollment is complete in the phase III EXTEND (PIX301) clinical trial of pixantrone (BBR2278) for patients with relapsed diffuse large B cell non-Hodgkin's lymphoma (NHL). An analysis of the data is expected in the second half of 2008. ***Based on prior discussions with the U.S. Food and Drug Administration (FDA) the data could provide a registration path for pixantrone*** if final study results are adequate for submitting a New Drug Application (NDA) with the FDA in early 2009 with a potential approval in 2009. A total of 140 patients were enrolled in the study, 97 patients are currently evaluable according to Histological Intent to Treat, or HITT, criteria and will be included in the final analysis of the study.

[Emphasis added]

72. This statement was materially false and misleading when made because CTI did not seek formal guidance from the FDA prior to informing the agency of its decision to stop the trial. According the Dr. Waxman, the FDA's representative at the ODAC meeting on March 22, 2010, "the decision was made without FDA input."

73. With regard to EXTEND's SPA, the press release stated:

> ***The study was conducted under a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA) and pixantrone has received fast track designation for this indication.***

[Emphasis added]

74. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree in writing (i.e., formally) that the

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

reduction in enrollment would not result in the SPA losing its validity; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. Therefore, Defendants intentionally or recklessly misrepresented the truth because "the study was" ***not*** "conducted under [an SPA] from the [FDA]." By misrepresenting and failing to disclose these material facts, the reference to the SPA in the press release materially misled investors by fostering the false impression that the FDA had agreed that the reduction in the number of participants in the study would not result in the SPA losing its validity, such that the benefit thereof was still available to the Company, even though it was not.

ii. CTI's Form 10-K for 2007, Filed March 26, 2008

75. On March 26, 2008 CTI filed its 2007 Form 10-K. The 2007 10-K reports that the EXTEND trial will close with 140 patients:

> An interim analysis of our ongoing phase III study of pixantrone, known as the EXTEND or PIX301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study continued. ***In September 2007, we announced that we reduced the enrollment target and decided to conduct a full analysis of the EXTEND trial, instead of an interim analysis as previously planned. In March 2008, we completed enrollment of approximately 140 patients in the EXTEND trial, 97 of which are currently evaluable according to Histological Intent to Treat, or HITT, criteria.*** An analysis of the data is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009. The FDA agreed that randomized safety data from the RAPID study (CHOP−R vs. CPOP−R) could be used to support the EXTEND results in an NDA submission for pixantrone. . . . An interim analysis of the RAPID study was reported in July 2007. The interim analysis of the study showed that to date a majority of patients on both arms of the study achieved a major objective anti−tumor response (complete response or partial response). . . . In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin.

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

76. The 2007 10-K also provided the following general description of the SPA process, at page 25:

> The FDA and IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA or BLA application. This process is known as special protocol assessment, or SPA. ***These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of an SPA, however, does not assure approval of a product candidate.***

[Emphasis added]

77. With regard to the risks associated with FDA trials, the 2007 10-K also stated only that:

> We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. ***Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product,*** withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

[Emphasis added]

78. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had already materially increased. By failing to disclose this known, specific, and identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

iii. November 3, 2008 Press Release

79. On November 3, 2008, the Company issued a press release entitled "Cell Therapeutics, Inc. Announces Study Data Set Cut-off for Phase III Pivotal Pixantrone (301) Trial." The press release stated, in relevant part:

> [CTI] announced today that it has closed the data set for preliminary analysis of the primary endpoint in the phase III EXTEND (PIX301) trial of pixantrone (BBR2278) for patients with relapsed diffuse large B cell non-Hodgkin's lymphoma (NHL) and it has provided Novartis notice that the data set has been closed. The primary endpoint for the study is the complete remission (CR) and unconfirmed complete remission (uCR) rate in patients receiving either pixantrone or another single agent chemotherapeutic drug. CTI plans to report top-line results in November.
>
> * * *
>
> ***The study was conducted under a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA) and pixantrone has received fast track designation for this indication.***

[Emphasis added]

80. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. Therefore, "the study was" ***not*** "conducted under [an SPA] from the [FDA]," and Defendants intentionally or recklessly misrepresented a material fact regarding the study to investors. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors by fostering the impression that the FDA agreed to the reduction in the number of participants in the study and

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

that the SPA was still valid, and therefore, the benefit thereof was still available to the Company, even though it was not.

iv. CTI's Form 10-Q for 3Q 2008, Filed November 7, 2008

81. On November 7, 2008, CTI filed its Form 10-Q for the third quarter of 2008 ended September 30, 2008. The form provided the following update on the EXTEND trial, at page 28:

> We are developing pixantrone, a novel anthracycline derivative, for the treatment of non-Hodgkin's lymphoma, or NHL. An interim analysis of our ongoing phase III study of pixantrone, known as the EXTEND or PIX301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study continued. ***In September 2007, we announced that we had reduced the enrollment target and decided to conduct a full analysis of the EXTEND trial, instead of an interim analysis as previously planned. In March 2008, we completed enrollment of approximately 140 patients in the EXTEND trial,*** 104 of whom are currently evaluable according to Histological Intent to Treat, or HITT, criteria. ***In November 2008, we announced that we closed the data set for preliminary analysis of the primary endpoint in the EXTEND trial and we plan to report top-line results in November 2008 as well. If final study results are adequate, we could begin a rolling submission of an NDA with the FDA in early 2009.*** The FDA agreed that randomized safety data from the RAPID study (CHOP−R vs. CPOP−R) could be used to support the EXTEND results in an NDA submission for pixantrone. The RAPID, or PIX203, study is a phase II study in which pixantrone is substituted for doxorubicin in the CHOP−R regimen compared to the standard CHOP−R regimen in patients with previously untreated diffuse large B-cell lymphoma. An interim analysis of the RAPID study was reported in July 2007. The interim analysis of the study showed that to date a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Patients on the pixantrone arm of the study had clinically significant reductions in the incidence of severe heart damage, infections, and thrombocytopenia (a reduction in platelets in the blood) as well as significant reduction in febrile neutropenia. In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin.

82. In the section devoted to risk factors, CTI added the following discussion of the EXTEND trial, at pg. 47:

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> On November 3, 2008, we announced that we had closed the data set for preliminary analysis of the primary endpoint in the phase III EXTEND (PIX301) trial of pixantrone for patients with relapsed diffuse large B cell non-Hodgkin's lymphoma and had also provided notice to Novartis that the data set has been closed. We have an existing license and co-development agreement with Novartis for OPAXIO which also provides Novartis with an option to enter into an exclusive worldwide license to develop and commercialize pixantrone based upon agreed upon terms. The primary endpoint for the PIX301 study is complete remission (CR) and unconfirmed complete remission (uCR) in patients receiving either pixantrone or another single agent chemotherapeutic drug.
>
> A third party contract research organization is currently reviewing this data and we expect them to provide us with preliminary top-line results shortly and to report such data in the fourth quarter. There can be no assurance that we will be able to complete our evaluation of or report data in such time frame. There can also be no assurance that the data, once reported, will be favorable or will be sufficient to demonstrate the safety and efficacy for purposes of obtaining FDA approval. If the primary endpoints of the PIX301 are not met, we will need to assess whether to continue to develop pixantrone. ***If the primary endpoints are met, there can be no assurance that such preliminary top-line results will not be affected by further analysis of the data, that we will have sufficient resources to continue to pursue FDA approval of Pixantrone or that such results will be sufficient to support an NDA filing in 2009.*** Furthermore, there can be no assurance that Novartis would elect to exercise its option for pixantrone at such time or within the specified time period for doing so.

[Emphasis added]

83. These statements were materially false or misleading because CTI failed to disclose ***why*** there could be no assurance the study results would be sufficient to support an application. CTI only disclosed the possibility that the FDA would reject the NDA, even though the study hit its endpoints. However, there is always a possibility that the FDA could reject an application, even when an SPA has been followed to the letter. Merely stating that a particular adverse result is possible does not adequately disclose the true risk of that adverse result if there are specific facts known to or recklessly disregarded by the filer that materially affect the probability of the adverse result occurring. Here, there was no disclosure that the SPA for EXTEND was no longer valid, even though the loss of the SPA substantially increased the

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

probability that the FDA would reject the NDA, regardless of whether or not the study hit its endpoints. The loss of the SPA was known to Defendants and should have been disclosed. Defendants' failure to disclose the loss of the SPA misled investors by fostering the impression that the FDA had agreed to the reduction in the number of participants in the study, that the SPA was still in force, and that the benefit thereof was still available to the Company, even though it was not.

v. November 11, 2008 Press Release

84. On November 11, 2008, CTI issued a press release entitled "Cell Therapeutics' Pixantrone Phase III (EXTEND) Pivotal Trial Successful in Achieving Primary Endpoint: Complete Remission / Unconfirmed Complete Remission Rate 3.5 Fold Higher Compared to Standard Chemotherapy." The press release stated:

> [CTI] announced today that it achieved the primary efficacy endpoint of its phase III EXTEND (PIX301) trial of pixantrone (BBR2778) for patients with advanced, relapsed aggressive non-Hodgkin's lymphoma (NHL) based on a preliminary intent to treat efficacy analysis.
>
> * * *
>
> CTI plans to submit complete study data for presentation at a major scientific conference. ***CTI also intends to request a pre-NDA meeting with the FDA and expects to begin submission of a rolling New Drug Application (NDA) to the FDA in early 2009.***
>
> "This positive phase III study is validation of Cell Therapeutics Inc.'s capabilities in acquiring attractive drug candidates, and designing and implementing a successful phase III trial," said James A. Bianco, M.D., CEO of Cell Therapeutics. "These data are consistent with the extensive experience with pixantrone in our phase I and phase II studies and demonstrate the ability to offer patients with advanced, relapsed NHL the potential to obtain a clinically meaningful response like a complete remission, despite having failed multiple other courses of chemotherapy or immuno-chemotherapy."
>
> The EXTEND clinical trial is a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> The trial was conducted at 130 sites in 17 countries. ***The trial enrolled 140 patients and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician.*** The trial was designed to examine the complete remission (CR) or unconfirmed complete remission (uCR) rate, overall survival (OS) and progression-free survival (PFS). ***The study received Special Protocol Assessment approval from the U.S. Food and Drug Administration (FDA) in 2004 and pixantrone has received fast track designation for this indication.***

[Emphasis added]

85. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had received was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors by fostering the impression that the FDA had agreed that the reduction in the number of participants in the study would not result in voiding the and CTI losing the benefit of the SPA, even though it had not.

vi. January 27, 2009 Press Release

86. On January 27, 2009, CTI issued press release entitled "Pixantrone Pre-NDA Communication from FDA Provides Cell Therapeutics Basis to Begin Rolling NDA Submission." The press release stated:

> [CTI] announced today that ***after communication with the Food and Drug Administration (FDA)***, CTI expects to begin submission of a rolling New Drug Application (NDA) and request priority review for pixantrone to treat relapsed aggressive non-Hodgkin's lymphoma (NHL) in the first quarter of 2009. If

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> granted priority review a decision on the NDA could occur before the end of 2009.
>
> "This communication from the FDA is a significant milestone for the Company and for patients with relapsed aggressive NHL as this could be the first drug approved for this unmet medical need," noted James A. Bianco, M.D. Chief Executive Officer of CTI. "With the potential for three drug approvals in 2009 we are on track to meet our objective of cash flow break even in the fourth quarter of this year."
>
> The EXTEND clinical trial was a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. ***The trial enrolled 140 patients and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician.***
>
> * * *
>
> ***The study received Special Protocol Assessment approval from the U.S. Food and Drug Administration (FDA) in 2004 and pixantrone has received fast track designation for this indication.***

[Emphasis added]

87. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had received was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

vii. January 28, 2009 Press Release

88. On January 28, 2009, CTI issued a press release entitled "Pixantrone Increases Progression-Free Survival by 81% Compared to Standard Chemotherapeutic Agents in Phase III Relapsed Aggressive non-Hodgkin's Lymphoma Trial." The press release announced preliminary results from EXTEND trial. The press release stated:

> [CTI] announced today preliminary progression-free survival (PFS) results from its pivotal phase III EXTEND (PIX301) trial of pixantrone that show patients with advanced, relapsed aggressive non-Hodgkin's lymphoma (NHL) treated with pixantrone experienced a statistically significant improvement in median progression-free survival, compared with other single-agent chemotherapeutic agents (4.7 months vs. 2.6 months, $p < 0.01$, pixantrone vs. standard chemotherapy) based on an intent to treat analysis. PFS was a prospectively defined secondary endpoint in the study.
>
> "We always believed the effectiveness of pixantrone would translate into a meaningful difference for patients with relapsed aggressive NHL and these dramatic and significant differences in PFS in this tough to treat group of patients provides that evidence," stated James A. Bianco, M.D. Chief Executive Officer of CTI. "Pixantrone is the first agent in this patient population to demonstrate a significant and meaningful PFS advantage. We believe these data will support a priority review designation on our New Drug Application (NDA) once we share them with the Food and Drug Administration (FDA)."
>
> * * *
>
> The EXTEND clinical trial is a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. ***The trial enrolled 140 patients*** and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician. The trial was designed to examine the complete remission or unconfirmed complete remission rate, overall survival and progression-free survival. ***The study received Special Protocol Assessment approval from the FDA in 2004 and pixantrone has received fast track designation for this indication.***
>
> ***The Company announced on January 27, 2009 that after a pre-NDA communication with the FDA, it expects to begin submission of a rolling NDA and request priority review for pixantrone to treat relapsed aggressive NHL in the first quarter of 2009.***

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

[Emphasis added]

89. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had received was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

90. The press release also contained the following discussion of risk factors:

> [T]he risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with pixantrone in particular[,] including . . . a determination by the FDA that the PIX301 trial is insufficient to support an NDA filing and that the FDA would grant priority review . . . .

91. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

Pixantrone would not be approved had already materially increased due to the invalidation of the SPA. By failing to disclose this known risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

viii. February 10, 2009 Press Release

92. On February 10, 2009, CTI issued a press release entitled "Cell Therapeutics and IDIS Announce Agreement for a European Named Patient/Compassionate Use Program for Pixantrone." The press release stated:

> [CTI] today announced that they have executed a definitive collaborative agreement with IDIS to manage its investigational drug pixantrone on a named patient basis in Europe. Pixantrone will be supplied by IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin's lymphoma. This program is expected to be initiated by second quarter of 2009.
>
> "Under the named patient program, CTI will be able to provide pixantrone to European patients in need at the prescriber's request while moving it through the approval process in the United States," noted Craig Philips, President of CTI. "With the announcement of preliminary results showing significantly higher rate of complete remission and improvement in progression-free survival for patients receiving pixantrone compared to standard chemotherapeutic agents, we expect to receive a number of requests for pixantrone to treat specific patients."
>
> "Pixantrone is an important new treatment with impressive remission and progression-free survival data," said Dr. Raul Herbrecht of Strasbourg University Hospital in France. "This drug is also important because it meets an unmet medical need for this group of patients. I have been impressed by the good tolerance and efficacy of pixantrone since the first clinical trial we had with this drug in our department. We obtained excellent results in salvage therapy of non-Hodgkin's lymphoma in heavily pretreated patients and several years later some of our patients are still in complete response. These positive results have been confirmed in further studies," Dr Herbrecht added.
>
> The EXTEND clinical trial was a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> ***The trial enrolled 140 patients and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician.***
>
> "We are pleased to be working with Cell Therapeutics to ensure that those patients with non-Hodgkin's Lymphoma who do not respond to current available therapies have access to pixantrone through a named patient program," said Natalie Douglas, CEO, IDIS. "CTI's potentially life-saving medicine can offer these patients renewed hope for remission. We are deeply committed to work in partnership with pharmaceutical and biotechnology companies to give physicians and their patients access to new and innovative medicines through regulated and responsible channels."
>
> * * *
>
> ***The study received Special Protocol Assessment approval from the U.S. Food and Drug Administration (FDA) in 2004 and pixantrone has received fast track designation for this indication.***

[Emphasis added]

93. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had received was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

94. The press release also contained the following discussion of risk factors:

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> [T]he risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with pixantrone in particular[,] including, without limitation, the results of complete safety information, the ability of the company to initiate named patient sales by the second quarter of 2009, the failure to receive anticipated number of requests for pixantrone to treat specific patients, the potential failure of pixantrone to prove safe and effective for treatment of relapsed aggressive NHL as determined by the FDA, the [C]ompany's ability to continue to raise capital as needed to fund its operations, competitive factors, technological developments, costs of developing, producing and selling pixantrone, and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's most recent filings on Forms 10-K, 8-K, and 10-Q. Except as may be required by law, CTI does not intend to update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

95. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially increased. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

ix. February 18, 2009

96. On February 18, 2009, CTI issued a press release entitled "Compared to Standard Therapies, Pixantrone Decreases Time to Achieve Complete Remission by 47% in Relapsed Aggressive Non-Hodgkin's Lymphoma: Phase III safety data underscores clinical benefit of Pixantrone." The press release announced:

> [CTI] announced today that updated safety and efficacy data from the phase III trial of pixantrone provides further support for a robust clinical benefit for pixantrone when used as single agent therapy in the treatment of multiple relapsed aggressive non-Hodgkin's lymphoma (NHL).
>
> * * *
>
> "We were impressed to see that 84% of patients received at least 5 cycles of pixantrone therapy with a median total dose of 1,475 mg, despite having had significant prior therapy with doxorubicin, an agent in a similar class with cumulative cardiotoxicity," noted Jack Singer, M.D., Chief Medical Officer at CTI. "The rapid time-to-response data coupled with the relatively low incidence of traditional anthracycline toxicities and a safety profile that compares favorably to standard chemotherapy, positions pixantrone to live up to the promise of providing patients with relapsed aggressive NHL a meaningful clinical benefit."
>
> ***CTI announced in November 2008 that it had achieved the primary efficacy endpoint of its phase III EXTEND (PIX301) trial of pixantrone (BBR2778).*** Patients randomized to treatment with pixantrone achieved a high rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy (14/70 (20.0%) for pixantrone arm compared to 4/70 (5.7%) for the standard chemotherapy arm, p = 0.02). No patient (0%) in the standard chemotherapy arm achieved a confirmed complete remission compared to 8/70 (11%) of pixantrone recipients.
>
> CTI expects to begin submission of a rolling New Drug Application (NDA) and request priority review for pixantrone to treat relapsed aggressive non-Hodgkin's lymphoma (NHL) in the first quarter of 2009. If granted priority review a decision on the NDA could occur before the end of 2009.
>
> ***The study received Special Protocol Assessment approval from the U.S. Food and Drug Administration (FDA) in 2004, and pixantrone has received fast track designation for this indication.***

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

97. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had received was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

98. The press release also contained the following discussion:

> This press release includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results. Specifically, the risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with pixantrone in particular including the potential failure of pixantrone to prove safe and effective for treatment of relapsed aggressive NHL as determined by the FDA, the Company's ability to continue to raise capital as needed to fund its operations, competitive factors, technological developments, costs of developing, producing and selling pixantrone, and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's most recent filings on Forms 10-K, 8-K, and 10-Q.

99. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially increased. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

x. CTI's Form 10-K for 2008, Filed March 16, 2009

100. On March 16, 2009, CTI filed its 2008 Form 10-K for the period ended December 31, 2008. The Company provided the following report on the progress of the EXTEND trial, at page 2:

> We are developing pixantrone (BBR 2778), a novel DNA major groove binder with an aza-anthracenedione molecular structure, differentiating it from anthracycline chemotherapy agents. A new chemical compound for the treatment of non-Hodgkin's lymphoma, or NHL, and various other hematologic malignancies, solid tumors, and immunological disorders, pixantrone is being developed to improve activity and safety in treating cancers currently treated with the anthracycline family of anti-cancer agents. ***Based on the outcome of our phase III EXTEND, or PIX 301, clinical trial, as described below, and on the basis of pre-NDA communication we received from the Food and Drug Administration, or FDA, relating to that phase III trial, we expect to begin a rolling New Drug Application, or NDA, submission to the FDA in the first half of 2009.*** If the NDA is granted priority review status, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.
>
> Pixantrone was studied in our EXTEND, or PIX301, clinical trial which is a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. An interim analysis of the EXTEND study of pixantrone was performed by the independent Data Monitoring Committee in the third quarter of 2006 and the study was continued based on that

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

review. ***The trial enrolled 140 patients who were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population, as selected by the physician. In November 2008, we announced that this trial achieved the primary efficacy endpoint.*** Patients randomized to treatment with pixantrone achieved a significantly higher rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy, had a significantly increased overall response rate, experienced a statistically significant improvement in median progression free survival and had a low incidence of certain side effects, including severe neutropenia complicated by either fever or documented infections, severe vomiting or diarrhea and hair loss, a very common side effect of other drugs in this class. Overall, the incidence of serious adverse events was similar between pixantrone and the control arm. The pixantrone patients had a higher incidence of leucopenia and neutropenia and numerically more severe cardiac events than in the control arm. Disease progression reported as an adverse event was less frequent in the pixantrone arm than in the control arm.

In February 2009, we entered into an agreement with IDIS Limited, or IDIS, to manage pixantrone as an investigational drug on a named patient basis in Europe. Pixantrone will be supplied by IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin's lymphoma. The program is expected to be initiated by the second quarter of 2009.

101. The Company also discussed in the 2008 Form 10-K that the FDA's agreement that the RAPID data could be used to supplement an NDA based on the EXTEND trial, stating, at pages 6-7:

We also conducted the RAPID, or PIX203, phase II study (CHOP−R vs. CPOP−R) in which pixantrone is substituted for doxorubicin in the CHOP−R regimen compared to the standard CHOP−R regimen in patients with aggressive NHL. Preliminary results of this trial were reported at the 49th Annual Meeting of the American Society of Hematology, or ASH, in December 2007. The interim analysis, in which 78 patients were evaluated for safety and 40 of the 78 patients were evaluated for efficacy, was reported in July 2007. ***The FDA agreed that randomized safety data from the RAPID study could be used to support the EXTEND results in an NDA submission for pixantrone.*** In early 2008, we closed enrollment on the RAPID study, based on adequate sample size to demonstrate difference in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. We expect to report results from this trial in the fourth quarter of 2009.

Based on the results of our EXTEND trial and pre-NDA communications from the FDA in January 2009 relating to the EXTEND trial, we expect to begin a

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> ***rolling NDA submission to the FDA for pixantrone in the first half of 2009.*** If the NDA is granted priority review status, the FDA could provide us with a decision on the NDA before the end of 2009.

102. The 2008 Form 10-K also provides the following description of the SPA process, at page 16:

> The FDA and IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as special protocol assessment, or SPA. ***These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of an SPA, however, does not assure approval of a product candidate.***

103. The 2008 Form 10-K also provided the following discussion of risk factors facing the Company, at page 24:

> We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. ***Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product***, withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.
>
> Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. . . . ***[W]e expect to begin submission of a rolling NDA to the FDA and request priority review for pixantrone to treat relapsed aggressive NHL in the first half of 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.*** Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. In addition, data obtained from clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business and financial condition will be adversely affected.

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

104. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially increased. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

105. These statements were materially false or misleading because they failed to disclose the invalidation of the SPA for the EXTEND trial. The loss of the SPA was known to Defendants and should have been disclosed, and Defendant's failure to disclose the loss of the SPA misled investors by fostering the false impression that the FDA agreed that the reduction in the number of participants in the study would not void the SPA and CTI would have the benefit of it, even though CTI would not.

xi. April 14, 2009 Press Release

106. On April 14, 2009, CTI issued a press release entitled "Cell Therapeutics Initiating Rolling NDA Submission for Pixantrone." The press release announced:

> [CTI] announced today that it began a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for pixantrone to treat relapsed or refractory aggressive non-Hodgkin's lymphoma

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> (NHL). CTI expects to complete the submission this quarter and will request priority review which if granted could lead to an approval decision from the FDA in Q4 2009.
>
> "This is a significant milestone for CTI as we move pixantrone closer to addressing a truly significant unmet medical need for relapsed or refractory aggressive NHL patients," said James A. Bianco, M.D., CEO of CTI. "The commercialization of pixantrone will drive shareholder value as a result of the large market potential for this product. We believe that the recent significant investment in CTI by a single institutional investor reflects a growing interest in CTI and in particular in pixantrone by the investment community. With added financial resources, CTI can advance pixantrone through the NDA review process while we continue our progress on strategic business development opportunities and relationships."
>
> * * *
>
> ***The pixantrone study received Special Protocol Assessment approval from the FDA in 2004, and pixantrone has received fast track designation for this indication.*** The FDA's fast track programs are intended to expedite the review of drugs that treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The rolling submission process enables companies that have been granted fast track designation to submit sections of the NDA to the FDA as they become available, allowing the review process to begin before the complete dossier has been submitted.

[Emphasis added]

107. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "[t]he study ***received*** [SPA] approval from the [FDA]" was materially false and misleading due to Defendants' omission of the fact that the SPA CTI had was now void. Moreover, the study that was actually performed – the study of only 140 patients – had never "received" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

108. The press release also contained the following discussion of risk factors:

> This press release includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results. Specifically, the risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with Pixantrone in particular including the potential failure of pixantrone to prove safe and effective for treatment of relapsed aggressive NHL as determined by the FDA, the possibility that the NDA submission will not be completed in the second quarter of 2009, that priority review is not granted and that a decision by the FDA is not rendered in late 2009, the Company will be able to complete strategic partnerships, the Company's ability to continue to raise capital as needed to fund its operations, competitive factors, technological developments, costs of developing, producing and selling pixantrone, and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's most recent filings on Forms 10-K, 8-K, and 10-Q.

109. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially increased. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

xii. In July 2009, CTI commenced a public offering without disclosing that the EXTEND study would no longer benefit from an SPA.

110. On July 23, 2009, the Company filed a Prospectus Supplement with the SEC. The Prospectus Supplement was dated July 22, 2009 and offered over 33.7 million shares of common stock (and over 8.4 million warrants to purchase additional shares of common stock) for sale at a price of $1.30 per share. The Prospectus Supplement was a supplement to a Prospectus dated April 6, 2009 and filed with the SEC on April 7, 2009. The Prospectus was filed in connection with a Registration Statement filed with the SEC on April 6, 2009. Collectively, the Registration Statement, Prospectus, and Prospectus Supplement are referred to herein as the "Offering Materials".

111. The Prospectus, a copy of which was included when the Prospectus Supplement was filed with the SEC, includes the following discussion of Pixantrone and the EXTEND trial, at page 2:

> We are developing pixantrone (BBR 2778), a novel DNA major groove binder with an aza-anthracenedione molecular structure, differentiating it from anthracycline chemotherapy agents. A new chemical compound for the treatment of non-Hodgkin's lymphoma, or NHL, and various other hematologic malignancies, solid tumors, and immunological disorders, pixantrone is being developed to improve activity and safety in treating cancers currently treated with the anthracycline family of anti-cancer agents. ***Based on the outcome of our phase III EXTEND, or PIX 301, clinical trial, as described below, and on the basis of pre-NDA communication we received from the Food and Drug Administration, or FDA, relating to that phase III trial, we expect to begin a rolling New Drug Application, or NDA, submission to the FDA in the first half of 2009. If the NDA is granted priority review status, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.***

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> Pixantrone was studied in our EXTEND, or PIX301, clinical trial which is a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. An interim analysis of the EXTEND study of pixantrone was performed by the independent Data Monitoring Committee in the third quarter of 2006 and the study was continued based on that review. ***The trial enrolled 140 patients who were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population, as selected by the physician. In November 2008, we announced that this trial achieved the primary efficacy endpoint.*** Patients randomized to treatment with pixantrone achieved a significantly higher rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy, had a significantly increased overall response rate, experienced a statistically significant improvement in median progression free survival and had a low incidence of certain side effects, including severe neutropenia complicated by either fever or documented infections, severe vomiting or diarrhea and hair loss, a very common side effect of other drugs in this class. Overall, the incidence of serious adverse events was similar between pixantrone and the control arm. The pixantrone patients had a higher incidence of leucopenia and neutropenia and numerically more severe cardiac events than in the control arm. Disease progression reported as an adverse event was less frequent in the pixantrone arm than in the control arm.

[Emphasis added]

112. The Prospectus, at page 17, discusses the risks associated with FDA regulation:

> We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. ***Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product,*** withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.
>
> Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. In March 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review and we expect to receive an opinion from the EMEA by June 2009. ***In addition, we expect to begin submission of a rolling NDA to the FDA and request priority review for pixantrone to treat relapsed aggressive NHL in the first half of 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final***

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> ***submission of the NDA.*** Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. In addition, data obtained from clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business and financial condition will be adversely affected.

113. The Prospectus Supplement, at page S-1, referred to Pixantrone as one of CTI's product candidates, all of which were under development at the time.

114. The Prospectus Supplement, at page S-14, discusses the risks associated with the purchase of securities under this Prospectus Supplement, stating:

> We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. ***Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product,*** withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.
>
> Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. . . . ***[O]n April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL and completed the submission and requested priority review in June 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.*** Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. In addition, data obtained from clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business, financial condition and results of operations will be adversely affected.

[Emphasis added]

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

115. These Offering Materials were materially false and misleading when filed because Defendants failed to disclose that: (1) the Company's SPA for Pixantrone was invalidated by the fact that the study was terminated before fully enrolled and a planned interim analysis was not conducted; and (2) the FDA had not approved the early termination of Study PIX-301 or the statistical analysis defendants intended to apply to the results of the study. In addition, the Prospectus Supplement, at page S-34, incorporated by reference the Company's Form 10-K for the fiscal year ended December 31, 2008. As a result, the Offering Materials were materially false and misleading for the same reasons set forth above as those incorporated previous public filing by CTI with the SEC.

116. On July 28, 2009, CTI issued a press release entitled "Cell Therapeutics, Inc. Announces Closing of Public Offering of Common Stock and Warrants." The press release stated:

> [CTI] today announced the closing of its previously announced public offering of 33,731,923 shares of its common stock and warrants to purchase up to 8,432,981 shares of its common stock, including the underwriter's exercise of its overallotment option. ***The Company received approximately $40.3 million in net proceeds from the offering, after deducting underwriting discounts and commissions and estimated offering expenses.***

[Emphasis added]

xiii. September 16, 2009 Press Release

117. On September 16, 2009, CTI issued a press release entitled "18 Month Follow-up Data on Phase III Study of Pixantrone in Late Stage Relapsed or Refractory, Aggressive Non-Hodgkin's Lymphoma Continues to Demonstrate Significant Improvement in Complete Remission and Progression Free Survival Over Standard Chemotherapy; Update Also

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

Demonstrates 3.3-month Improvement over Standard Chemotherapy in Median Overall Survival." The press release stated:

> [CTI] today released updated 18-month follow-up clinical data for its phase III EXTEND (PIX 301) trial of pixantrone (BBR2778) for patients with advanced, relapsed or refractory, aggressive non-Hodgkin's lymphoma (NHL). Responses were evaluated by an Independent Assessment Panel that was blinded to patient assignment.
>
> * * *
>
> "We continue to be impressed by the durability of responses in the pixantrone treatment arm which seemed to improve during the study follow up period, compared to the standard chemotherapy recipients – whose responses and duration of response are largely unchanged from the initial assessment period," noted James A. Bianco, M.D., Chief Executive Officer of CTI. "We are also encouraged by the increase in the overall survival estimates, especially among those patients whose histologic diagnosis was verified by independent pathologists where 40% of pixantrone recipients were alive, compared to 27% for standard chemotherapy at the 1 year landmark period. We plan to submit these updated safety and efficacy data to our NDA as part of the 120 Day update."
>
> The FDA typically receives updated clinical study data 120 days following the initial NDA submission.
>
> The most common (incidence greater than or equal to 20%) adverse reactions reported for pixantrone-treated subjects were neutropenia, infection, anemia, leucopenia, thrombocytopenia, asthenia, pyrexia, and cough.
>
> Pixantrone has been accepted for standard review by the Food & Drug Administration (FDA), with fast track status with a Prescription Drug User Fee Act (PDUFA) date of April 23, 2010.
>
> * * *
>
> The EXTEND clinical trial is a phase III single agent trial of pixantrone for patients with relapsed or refractory, aggressive non-Hodgkin's lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. The trial was conducted at 130 sites in 17 countries. Patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population and selected by the physician. The trial was designed to examine the complete remission (CR) or unconfirmed complete remission (uCR) rate, time to tumor progression, and overall survival. ***The study was conducted under a Special Protocol Assessment***

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> ***from the U.S. Food and Drug Administration (FDA) and pixantrone has received fast track designation for this indication.***

[Emphasis added]

118. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, Defendants affirmatively misrepresented a material fact regarding the study by stating that "the study was conducted under [an SPA] from the [FDA]." Because the SPA was voided once the enrollment was closed in March 2008, "the study" was ***not*** "conducted under [an SPA] from the [FDA]." Indeed, the study that was actually performed – the study of only 140 patients – had never "[been] conducted under" an SPA from the FDA. By failing to disclose these facts, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

119. The press release also contains the following discussion of risk factors:

> This press release includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of the securities of CTI. Specifically, the risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general, and with pixantrone in particular, including, without limitation, the potential failure of pixantrone to prove safe and effective (including the failure to achieve the overall response rate, complete remissions and progression-free survival and the possibility of significant grade 3, 4 adverse effects, including cardiac disorders) for the treatment of relapsed or refractory, aggressive NHL as determined by the FDA, that CTI does not submit the 18-month follow-up data to the FDA as part of the 120-day update, and the possibility that the follow-up data does not demonstrate continued improvement in the primary and secondary endpoints, CTI's ability to continue to raise capital

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> as needed to fund its operations, competitive factors, technological developments, costs of developing, producing and selling pixantrone, and the risk factors listed or described from time to time in CTI's filings with the Securities and Exchange Commission including, without limitation, CTI's most recent filings on Forms 10-K, 10-Q and 8-K.

120. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the false impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially – if not to a certainty – already occurred. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

xiv. December 5, 2009 Earnings Call

121. On December 5, 2009, the Company held an earnings conference call with investors and analysts, during which Defendant J. Bianco stated as follows:

> A little bit on the pixantrone development history. . . . [We] took over the development of pixantrone, in terms of the clinical development at least, and that lead to our first end-of-phase meeting with the FDA in 2004. ***And at that time we devised what was called the PIX301 study that was done under a special protocol assessment procedure with the FDA.***

122. This statement was materially false and misleading when made because Defendant J. Bianco intentionally or recklessly failed to disclose that the SPA ceased to be valid

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

once the trial was closed in March 2008, having only enrolled 44% of the number of patients originally called for in the trial design. In addition, Defendant J. Bianco affirmatively misrepresented a material fact when he stated that "the [EXTEND] study [] ***was done*** under [an SPA] with the FDA." In fact, the study that was actually performed – the study of only 140 patients – had not been "done" under an SPA from the FDA. By failing to disclose this fact, the reference to the SPA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

123. Defendant J. Bianco continued to misrepresent that the FDA had agreed to the Company's plan to reduce the enrollment, stating:

> [The] Study was quite challenging from an enrollment perspective. We initially targeted 320 patients. ***We had discussions with the FDA, essentially cutting the enrollment back to a number where we felt would be adequate to still maintain the initial power assumptions in the trial. That was done in about 140 patients.*** That discussion happened in January of '07 and in '08 March we reached 140 patients and we terminated the enrolment in the trial.

124. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. Further, the statement that "[the Company] had discussions with the FDA" was materially false and misleading because the statement failed and omitted to disclose that the Company did not, in fact, receive any agreement from the FDA that the reduction in enrollment would not void the SPA and that, as a result of reducing enrollment from the number required by the SPA, the SPA was voided. By

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

failing to disclose these facts, the reference to the discussions with the FDA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

C. The Truth Begins to Emerge

i. The FDA's Briefing Document for the February 10, 2010 ODAC Meeting Reveals That the EXTEND Trial Had Not Been Conducted Pursuant to an SPA Since March 25, 2008.

125. On February 8, 2010, the FDA posted its analysis of the EXTEND study on the internet prior to the ODAC meeting, scheduled for February 10, 2010, to review the Company's NDA for Pixantrone. In the report, the FDA stated that the SPA had been invalidated ***in March 2008***:

> The pivotal trial, PIX301, was discussed at an End of Phase 2 meeting on October 8, 2003. At this meeting, FDA stated, "Accelerated approval could be based on an interim analysis of a surrogate endpoint with completion of the trial demonstrating an improvement on a clinical benefit endpoint (survival or symptom benefit)." FDA recommended that the trial assess complete response and the duration of complete response. Subsequently, agreement was reached concerning a Special Protocol Assessment for PIX301. ***On March 28, 2008, CTI notified the FDA of an early halt to enrollment for PIX301. The study was not stopped at a planned interim analysis and early study stopping invalidated the applicant's Special Protocol Assessment.*** The applicant subsequently analyzed their data and began submission of a rolling NDA on April 13, 2009 with the last module submitted on June 22, 2009.

[Emphasis added]

126. The FDA further criticized the Company's analysis of the data set, stating:

> ***The planned sample size was 320. However, the study stopped early at an unplanned time point, due to poor accrual.*** A higher level of evidence is usually required in trials which discontinue prior to the final analysis. Based on the Rho family error spending function (Rho parameter = 2) used in the sponsor's statistical analysis plan and with 44% of planned enrollment, the significance level allocated for the submitted analysis would be 0.0096 (0.0014 based on the

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> O'Brien-Fleming-type error spending function). ***Therefore, the submitted primary analysis would not be significant.***

[Emphasis added]

127. On February 8, 2010, TheStreet.com published a column by Adam Feuerstein entitled "FDA Tough on Cell Therapeutics' Drug." In the article, Mr. Feuerstein described how the ODAC report confirmed the concerns about CTI he had laid out in his article from February 1, 2010:

> Last week, I laid out in detail seven reasons why the U.S. Food and Drug Administration could decide to reject Cell Therapeutics' lymphoma drug pixantrone.
>
> On Monday, the FDA posted a substantially negative assessment of pixantrone in advance of Wednesday's FDA advisory panel meeting. The FDA review hits on almost all seven of the pixantrone concerns and problems I raised.
>
> The entire FDA review of pixantrone is posted to the agency's web site.
>
> Add it all up, and Cell Therapeutics faces a very difficult task convincing the FDA's panel of cancer experts to recommend pixantrone's approval as a treatment for patients with advanced, aggressive non-Hodgkin's lymphoma.
>
> Let's break down the issues I raised about pixantrone last week and see how that compares to what the FDA's reviewers said about the drug Monday:
>
> 1. Missing patients?
>
> Last week, I questioned whether the FDA would accept the "positive" results from the phase III "EXTEND" study of pixantrone given that Cell Therapeutics only enrolled 140 of a planned 320 patients.
>
> ***Recall that Cell Therapeutics has long claimed the FDA was OK with the smaller-than-expected enrollment in the study and that the study's statistical plan was adjusted accordingly. That turns out not to be true.***
>
> Monday, the FDA wrote:
>
> "The planned sample size was 320. However, the study stopped early at an unplanned time point, due to poor accrual. A higher level of evidence is usually required in trials which discontinue prior to the final analysis. Based on the Rho family error spending function (Rho parameter = 2) used in the sponsor's

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> statistical analysis plan and with 44% of planned enrollment, the significance level allocated for the submitted analysis would be 0.0096 (0.0014 based on the O'Brien-Fleming-type error spending function). Therefore, the submitted primary analysis would not be significant."
>
> Translation: The pixantrone study failed, even using Cell Therapeutics' own statistical plan due to the low patient enrollment. In order for the pixantrone study to have been positive and statistically significant, the "p value" generated by the final analysis needed to be lower than 0.0096. The actual "p value" was 0.021.
>
> 2. Does Cell Therapeutics really have a Special Protocol Assessment?
>
> A Special Protocol Assessment (SPA) is essentially a formal agreement reached between a drug company and the FDA that the design and endpoints of a phase III clinical trial are sufficient for a drug's approval.
>
> Cell Therapeutics executives, including CEO Jim Bianco, have stated repeatedly, in public, that the EXTEND study of pixantrone was conducted under an SPA from the FDA. Many of the company's recent press releases, including one from April 14, 2009, also make the claim.
>
> False!
>
> * * *
>
> ***How is Cell Therapeutics going to explain why it lied about having an SPA for the pixantrone study? An SPA was in place at one point in time, but Cell Therapeutics neglected to tell investors that the agreement was yanked.***
>
> Perhaps we now know why the company never mentioned having an SPA for the pixantrone study in its filings with the Securities and Exchange Commission, as I outlined last week.

[Emphasis added]

128. By the close of the market on Monday February 8, 2010, in response to the devastating revelation that CTI had invalidated the SPA in March 2008, the price of CTI stock had fallen $0.42 per share to close at $0.64 per share – a 39% decline from its previous closing price of $1.06 per share on Friday February 5, 2010, the previous trading day.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

129. The following day, on February 9, 2010, Forbes.com published a blog post entitled "FDA Agreements Should Be Public." The blog post reported on the February 8, 2010 release of the FDA's briefing document, stating:

> Cell Therapeutics (CTI) shares fell 40% to 60 cents yesterday after [a] briefing document prepared by the FDA raised multiple problems with the company's drug, pixantrone, and the quality of the clinical trials Cell Therapeutics is using to argue for its approval as a treatment for non-Hodgkin's Lymphoma. ***The biggest shocker, though, related to an agreement called a "special protocol assessment" which the company had told investors it had but which the FDA now says is no longer valid.***

[Emphasis added]

ii. CTI Continues to Mislead the Public

a) February 9, 2010 Press Release

130. On February 9, 2010, Defendants misleadingly attempted damage control by issuing a press release announcing postponement of ODAC meeting due to severe weather conditions. The press release quotes Defendant J. Bianco as saying, "We are pleased with the time that the FDA has invested in connection with its review of our application for pixantrone. ***We believe that many of the key issues they identified are addressed in our own briefing material which is now publically available as well.***" The press release also notes that "the risks and uncertainties that could affect the development of pixantrone include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general, and with pixantrone in particular, including, without limitation, . . . that CTI's briefing materials do not address all of the key issues the FDA may have with the pixantrone NDA." The press release, however, failed to address Defendants' long-standing knowledge that their unilateral alteration of the number of patients enrolled in EXTEND was not agreed to by the FDA and that they

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

knew, by March 2008, that the SAP was void. Defendants' failure to address the invalidation of the SPA was a material omission from the press release.

131. The document to which Defendant J. Bianco referred in the press release was a CTI briefing document entitled "Oncologic Drugs Advisory Committee Meeting Briefing Document" that had been filed by CTI with the FDA on January 6, 2010 in anticipation of the ODAC meeting, which at that point was scheduled for February 10, 2010. The briefing document repeatedly mentions that the EXTEND study received an SPA. At pages 4 through 5, the briefing document describes the EXTEND study design, stating in relevant part:

> Prior to its initiation, the pivotal study protocol (PIX301, CTI Study) was reviewed under the Special Protocol Assessment (SPA) process with the Division of Oncologic Drug Products (DODP).
>
> * * *
>
> All analyses conducted were described in the statistical analysis plan and agreed to by FDA during the SPA process.

132. At page 6, the Company discussed the close of the EXTEND trial, and again implied that the Company had reached a formal agreement with the FDA that would preserve the validity of the SPA:

> Enrollment in PIX301 was slow, and despite several measures aimed at enhancing accrual (widening inclusion criteria, opening 100 additional sites in 15 additional countries) ***a decision was made, following discussion with the FDA, to close enrollment after the 140th patient was randomized, 45 months from the start of the study.*** The planned interim analysis was cancelled; only one analysis was conducted per the original statistical analysis plan. The Sponsor remained blinded to treatment assignment until database lock in February 2009.

[Emphasis added]

133. At page 43, the CTI briefing document discussed the statistical methods used in the EXTEND study and states that "[s]tatistical analysis methodology remained unchanged from the statistical analysis plan submitted and reviewed by the FDA in the SPA review process."

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

134. At pages 48 through 49, the CTI briefing document described the regulatory history of the Pixantrone NDA, stating in relevant part:

> During the development of pixantrone, CTI sought the advice of the FDA's Division of Oncology Drug Products (DODP) in a series of meetings and other interactions related to the phase 3 program in aggressive NHL. Requirements for registration in relapsed, refractory aggressive NHL were initially addressed in an end-of-phase 2 meeting, and during the Special Protocol Assessment (SPA) interactions, agreements were reached on the following:
>
> - Patient population suitable for a randomized trial design
> - Selection of CR/CRu as the primary endpoint and selection of secondary endpoints (duration of response, overall response, PFS and OS
> - Choice of comparator agents
> - Statistical analysis plan
>
> In July 2007, CTI discussed with FDA the possibility of halting the phase 3 study, PIX301, because of slow enrollment. . . . In March 2008, after enrolling 140 patients between June 2004 and March 2008 for an enrollment rate of 3.1 patients per month, CTI notified FDA of their decision to halt enrollment in PIX301 due to the inability to alter enrollment rates adequately to achieve the planned target of 320 patients within a reasonable timeframe. In May 2008, CTI submitted to the FDA a revised PIX301 statistical analysis plan to reflect the early halt of enrollment and cancellation of the planned interim analysis. ***Although the sample size was reduced, the original statistical analysis plan and statistical methods for data analyses, previously agreed upon with the FDA, remained the same.***

[Emphasis added]

135. The statements made by Defendant J. Bianco in the February 9, 2010 press release regarding the CTI briefing document were materially false and misleading when made because the CTI briefing document to which he referred certainly "addressed" the "key issue" of the SPA, but did so in a manner intended (a) to avoid admitting that Defendants knew that the SPA ceased to have any force since March 2008, and (b) to foster the false impression that CTI had secured agreement from the FDA that the reduced number of patients would not invalidate the SPA. Even though the briefing document repeatedly highlighted the fact that the EXTEND

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

study was originally granted an SPA, it fails to disclose that the SPA ceased to be effective in March 2008, when CTI closed enrollment at 140 patients. Instead, the statements were designed to give the false impression that, "following discussion with the FDA," the study was cut short with the FDA's agreement that it would not void the SPA. In fact, the FDA had never agreed to permit CTI to reduce enrollment and retain the SPA.

b) CTI's 2009 Form 10-K, Filed February 26, 2010

136. On February 26, 2009, CTI filed its 2009 Form 10-K for the period ended December 31, 2009. In its discussion of the EXTEND trial, CTI makes no mention of the SPA:

> We are developing pixantrone, a novel anthracycline derivative, for the treatment of non-Hodgkin's lymphoma, or NHL, and various other hematologic malignancies, solid tumors and immunological disorders. Pixantrone was studied in our EXTEND, or PIX301, clinical trial, which is the first randomized, controlled, phase III single-agent clinical trial of pixantrone for patients with relapsed, aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. ***In November 2008, we announced that this trial achieved the primary efficacy endpoint. Based on the outcome of the EXTEND trial and on the basis of a pre-New Drug Application, or NDA, communication we received from the U.S. Food and Drug Administration, or FDA, relating to this phase III trial, we began a rolling NDA submission to the FDA in April 2009.*** We completed the submission in June 2009 and we have been notified by the FDA that a Prescription Drug User Fee Act, or PDUFA, action date of April 23, 2010 under standard review has been established. Based on this PDUFA date, if pixantrone is approved, it could be available to patients in the United States as early as the second quarter of 2010.

[Emphasis added]

137. This statement was materially false and misleading when made because Defendants failed to disclose: (i) that the FDA did not agree to the reduction in enrollment; and (ii) that the SPA ceased to be valid once the trial was closed having only enrolled 44% of the number of patients originally called for in the trial design. In addition, the statement that "on the basis of a [pre-NDA] communication we received from the [FDA] relating to [EXTEND],

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

we began a rolling NDA submission to the FDA in April 2009" was materially false and misleading because the Company did not, in fact, have any agreement from the FDA that the reduction in enrollment would not void the SPA. Moreover, this discussion of the EXTEND trial fails to correct the false statement made by Defendant J. Bianco in the December 5, 2009 earnings call that "the PIX301 study that ***was done*** under a special protocol assessment procedure with the FDA," nor does it disclose that CTI no longer had its previously touted SPA due to its unilateral deviation from the SPA's terms. By failing to disclose these facts, the reference to the discussions with the FDA in the press release materially misled investors (i) by fostering the false impression that the FDA agreed to the reduction in the number of participants in the study, and (ii) by not disclosing that CTI had violated the SPA and lost the benefit thereof, even though it had.

138. The 2009 10-K included the following description of the SPA process, at page 16:

> The FDA and IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as a special protocol assessment, or SPA. ***These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of an SPA, however, does not assure approval of a product candidate.***

[Emphasis added]

139. The 10-K included the following discussion of risk factors that could impact the company:

> We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. ***Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product,*** withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. ***On April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL. We completed the submission in June 2009 and we have been notified by the FDA that a PDUFA action date of April 23, 2010 under standard review has been established.***

[Emphasis added]

140. These statements were materially false or misleading because CTI failed to disclose that the invalidation of the SPA for the EXTEND trial had already occurred. The loss of the SPA was a known, existing fact that should have been disclosed, and Defendants' failure to disclose the loss of the SPA misled investors by fostering the impression that the SPA for the EXTEND study was still in force and the benefit thereof was still available to the Company, even though it was not. Further, Defendants' boilerplate statements regarding the risks of regulatory oversight failed to disclose that, because CTI's SPA was void, the risk that Pixantrone would not be approved had materially increased. By failing to disclose this known, existing, and specifically identifiable risk – and the facts giving rise to the significantly increased risk of non-approval – Defendants misled the public to believe that CTI was still performing under a valid SPA and that, based on its disclosures of the positive indications from EXTEND and RAPID, approval of Pixantrone was likely.

c) March 1, 2010 Press Release

141. On March 1, 2010, CTI issued a press release announcing that the ODAC meeting would take place on March 22, 2010. In the press release, Defendant J. Bianco stated, "Our team is well-prepared to deliver an evidenced-based presentation to the ODAC panel, which we expect will provide a persuasive argument to the clinicians on the panel for the approval of

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

pixantrone." Bianco continued, "The ODAC meeting is an important milestone in the review process, and we look forward to discussing the efficacy and safety data for pixantrone with the members of the panel and the FDA review team."

iii. The Full Truth Comes Out at the March 22, 2010 ODAC Hearing

142. On March 22, 2010, the ODAC met to discuss the Pixantrone New Drug Application ("NDA"). The public hearing was closely covered by investors and analysts. At the meeting, the FDA representative, Dr. Waxman, stated that CTI violated the SPA when CTI closed enrollment at 140 patients and that CTI did not ask for any formal guidance from the FDA prior to closing the study:

> In March of 2008, approximately four years after initiation of the Phase 3 trial, CTI notified the FDA of its decision to stop enrollment with less than half of planned enrollment completed. The applicant stated that the trial was stopped early as a result of poor accrual and the stop did not occur as the result of a safety finding or the crossing of an efficacy boundary.
>
> ***CTI did not seek formal guidance from the FDA prior to informing the agency of its decision to stop the trial. The decision was made without FDA input. This early stopping of the trial at less than half of planned enrollment was considered to be a major deviation in the conduct of the trial, and as a result, any agreements that had been reached during the SPA process were invalidated.***

[Emphasis added]

143. Later during that meeting, the ODAC voted ***unanimously*** that CTI's clinical trial data was not adequate to support the approval of Pixantrone. As reported by *Bloomberg*:

> Cell Therapeutics Inc. failed to win a U.S. panel's backing to sell its experimental drug Pixuvri for aggressive non-Hodgkin's lymphoma. Outside advisers to the Food and Drug Administration said in a 9-0 vote today in Gaithersburg, Maryland, that Cell Therapeutics' single incomplete trial isn't sufficient to support approval of the medicine. While the FDA usually follows its advisers' recommendations, it isn't required to do so.
>
> Last month, FDA staff questioned a study of Pixuvri that was stopped halfway through because not enough people enrolled, sending Cell Therapeutics shares to

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

> their biggest decline in 10 months. Some of the advisers suggested today that the company should go back and test the injection in combination with other drugs instead of as a single treatment in patients who have failed two previous therapies for the deadly form of cancer.
>
> "There's no evidence that this drug may be better than or worse than or equivalent to what we already have out there," said panel member Wyndham Wilson, chief of lymphoma therapeutics at the National Cancer Institute's research center in Rockville, Maryland. "It's an interesting agent" he said, also noting that "it's still way too early" for approval.

144. By the close of the market on Monday March 22, 2010, the price of CTI stock fell $0.44 per share to close at $0.47 per share – a 48% decline from its previous closing price of $0.91 per share on Friday March 19, 2010, the previous trading day.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

A. Defendants J. Bianco and L. Bianco Expressly Admitted That They Were Aware That the SPA Was Void

145. Statements to CW1 establish that Defendants J. Bianco and L. Bianco were well-aware that the EXTEND SPA was void as of the March 2008, when the enrollment in the EXTEND trial was closed with only 140 patients – less than half the number of patients originally called for in the trial design. In March 2008 when the enrollment number was reduced, CW1 personally met with Defendants J. Bianco and L. Bianco and made sure that they understood that because the protocol had been changed, the SPA was no longer active. CW1 stated that Defendants J. Bianco and L. Bianco informed her that they were aware that the EXTEND trial would proceed without the benefit of an SPA.

B. The Individual Defendants, by Reason of Their Roles at the Company and Professional Background, Were Aware That the SPA Was Void

146. The Individual Defendants' knowledge that the EXTEND SPA was void as of March 2008, when enrollment in the EXTEND trial was closed at only 140 patients – less than half the amount originally called for by the trial's design – is also established by the nature of

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

the Individual Defendants' roles in the Company and their professional backgrounds and experience. Each Individual Defendant had a detailed knowledge of the SPA process in general and its requirements, such that they knew that the SPA was void once CTI determined to deviate from its terms by closing enrollment in the study in March 2008 with less than the required number of patients. Therefore, the Individual Defendants knew or recklessly disregarded the fact that the statements issued by them and/or by CTI during the Class Period – detailed above – regarding the EXTEND study, the previously granted SPA, and the risks associated with the approval of Pixantrone were materially false and misleading.

147. Defendant J. Bianco would was well-aware of the SPA process, including the consequences of the material departure from the number of patients called for in a trial's study design. Defendant J. Bianco holds an M.D. from Mount Sinai School of Medicine and, prior to founding CTI, was an Assistant Member in the clinical research division of the Fred Hutchinson Cancer Research Center and an Assistant Professor of Medicine at the University of Washington. In addition, from 1990 to 1992, Defendant J. Bianco was the director of the Bone Marrow Transplant Program at the Veterans Administration Medical Center in Seattle. This professional background gave Defendant J. Bianco a knowledge base that informed him of the requirements to maintain an SPA and he knew or recklessly disregarded the fact that the SPA was void as of the close of enrollment in March 2008. Moreover, as CTI's founder and senior-most executive officer, Defendant J. Bianco was intimately knowledgeable about the terms of the SPA. According to CW2, Defendant J. Bianco was one of the employees at CTI who spoke directly with the FDA.

148. Defendant J. Bianco, as CEO of CTI, was the chief architect of the Company's portfolio strategy, leading the acquisition, development, and commercialization of Pixantrone.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

He was also responsible for raising operating capital the Company needed to take Pixantrone through the FDA approval process. In addition, he was the chief public spokesperson for the Company. Defendant J. Bianco signed each of the Company's SEC filings during the Class Period, participated in the Company's earnings calls, and provided quotes for the Company's press releases. According the CW1, Defendant J. Bianco was a "hands on" type of executive. According to CW2, Defendant J. Bianco regularly came to the Clinical Development and Regulatory Department, especially when the Pixantrone trials were in trouble.

149. Defendant L. Bianco was the Executive Vice President of Finance and Administration for the Company. Defendant L. Bianco is Defendant J. Bianco's brother and a co-founder of the Company. From January 1989 through January 1992, Defenant L. Bianco was a Vice President at Deutsche Bank Capital Corporation in charge of risk management. Defendant L. Bianco is a Certified Public Accountant and received his M.B.A. from New York University. As a result, Defendant L. Bianco was intimately involved in all material aspects of the FDA approval process for Pixantrone and responsible for overseeing its costs. Indeed, according to CW1, Defendant L. Bianco was also a "hands on" type of executive. According to CW2, Defendant L. Bianco was "always in the [Clinical Development and Regulatory Affairs Department] and was constantly talking with [CW1, the VP of Clinical Development and Regulatory Affairs]." Defendant L. Bianco also signed the each of the Company's the SEC filings during the Class Period.

150. Defendant Philips, as the President of CTI, was responsible for managing the Company's day-to-day drug development and commercial operations. Prior to joining CTI, Philips was Vice President and General Manager of Bayer Healthcare Oncology. Prior to Bayer Healthcare, Philips was the head of Berlex Oncology since 2004. Before Berlex, Philips was

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

with Schering Plough. He began his career with Bristol Myers, where he worked in a variety of therapy areas including oncology, cardiology, and CNS. This professional background gave Defendant Philips a thorough knowledge of the FDA approval process, including the requirements for maintaining an SPA, and the fact that the EXTEND SPA was void as of the close of enrollment in March 2008.

C. The Individual Defendants, by Reason of Pixantrone Being a Core Product of the Company, Were Aware That the SPA Was Void

151. Because Pixantrone was an essential, core product for the Company, the Individual Defendants were well-aware that the SPA was void as of March 2008 and that all subsequent references to the EXTEND trial were intentionally or recklessly misleading and false in light of the loss of the SPA. As noted in the Company's 2007 10-K, filed on March 26, 2008, Pixantrone was one of only four products on which the Company was focusing its efforts at the beginning of the Class Period (the others were Zevalin, paclitaxel poliglumex, and brostallicin). Pixantrone continued to be a top priority of the Company throughout the Class Period, as indicated by the Company's 2008 and 2009 10-Ks, filed on March 16, 2009 and February 26, 2010, respectively, each of which stated that the Company was "focusing [its] efforts on pixantrone, OPAXIO, brostallicin[,] and bisplatinates." Further, as the three senior executives of the Company, the Individual Defendants were aware of any and all significant developments related to this pivotal product, Pixantrone. In particular, the Individual Defendants knew or recklessly disregarded the material increase in the risk that Pixantrone would not be granted FDA approval because EXTEND was no longer being conducted under the SPA.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

D. The Company Had Substantial Motivation to Participate in the Fraudulent Practices Alleged Herein

152. Defendants had a substantial motivation to engage in the fraudulent practices alleged herein due to the Company's desperate need to raise new capital to survive as a going concern. The Company, in its 2007 Form 10-K, filed on March 26, 2008, revealed that:

> Due to our need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their report on our December 31, 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

These financial woes continued throughout the Class Period. The Company, in its 2008 Form 10-K, filed on March 16, 2009, and in its 2009 Form 10-K, filed on February 9, 2010, repeated the same warning from the 2007 10-K. Further, the extremely high cost of the EXTEND study and time it would take to complete as designed further exacerbated CTI's financial troubles.

153. Given CTI's financial problems and need for new infusions of capital to develop its products, CTI needed to keep its stock price as high as possible or face an inability to raise the additional money it needed to continue operations. Defendants knew that the value of CTI's securities would immediately plummet if the truth regarding the SPA for EXTEND was revealed, making attempts to raise additional funds far more difficult, if not virtually impossible, for the Company. Without continuing infusions of new money, CTI could not afford to continue its efforts to obtain FDA approval for Pixantrone or develop and commercialize any of its other potential products. Indeed, without such infusions of new capital, CTI's very survival as a going concern was at stake. Accordingly, to save time and money, Defendants' closed the EXTEND study's enrollment below the number required to maintain its SPA; repeatedly

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

assured the investment community that it would soon be filing the Pixantrone NDA based on the positive results from the EXTEND study; and throughout the Class Period continuously, through false statements and omissions, misled the investing public into believing that the EXTEND study was still subject to an SPA. This course of conduct allowed CTI to raise new capital throughout the Class Period based on artificially inflated valuations of its equity. Indeed, on May 7, 2008, CTI issued a press release stating that "[o]ur focus for the first half of 2009 was to initiate and complete the NDA submission for Pixantrone while we implemented final steps in our cost cutting efforts and raised much needed operating capital on the least dilutive terms possible – all while cleaning up the Company's capital structure."

154. During the Class Period, CTI raised over $216.4 million in new capital, as set forth below:

- June 12, 2008: CTI issued a press release announcing that a single institutional investor was partially exercising a previously granted warrant right to purchase CTI securities in a transaction that would generate net proceeds of $12.65 million from this transaction, after depositing amounts in escrow for the make-whole provision required by the notes.
- July 24, 2008: CTI issued a press release announcing that a single institutional investor was partially exercising a previously granted warrant right to purchase CTI securities in a transaction that would generate net proceeds of $44.5 million, prior to deducting amounts that would be put in escrow for a make-whole provision on the new notes and the repurchase of prior notes and warrants issued to the investor.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

- July 28, 2008: CTI issued a press release announcing that the Company received approximately $40.3 million in net proceeds from a public offering of 33,731,923 shares of its common stock and warrants to purchase up to 8,432,981 shares of its common stock.
- September 29, 2008: CTI issued a press release announcing a single institutional investor would purchase newly issued notes in a transaction that would generate net proceeds of approximately $5.4 million (before payment of fees and expenses), after depositing amounts in escrow for the make-whole provision required by the notes.
- October 22, 2008: CTI issued a press release announcing that a single institutional investor would purchase newly issued notes and sell back older notes in a transaction that would generate net proceeds of approximately $7.5 million (before payment of fees and expenses).
- December 5, 2008: CTI issued a press release announcing that a single institutional investor would purchase newly issued notes and sell back older notes in a transaction that would generate net proceeds of approximately $6.5 million (before payment of fees and expenses).
- April 13, 2009: CTI issued a press release announcing that a single institutional investor would purchase $15 million shares of preferred stock.
- May 11, 2009: CTI issued a press release announcing that a single institutional investor would purchase $20 million in shares and warrants.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

- August 19, 2009: CTI issued a press release announcing that CTI has entered into agreement to sell $30 million of preferred stock and warrants to a single institutional investor.
- January 13, 2010: CTI issued a press release announcing that it has entered into an agreement to sell $30 million shares of preferred stock and warrants to two institutional investors.

E. The Individual Defendants Had Substantial Motivation to Participate in the Fraudulent Practices Alleged Herein

155. The Individual Defendants had substantial motivation to participate in the fraudulent practices alleged herein. First, the Individual Defendants' compensation included cash bonuses that were contingent on raising capital and reaching certain regulatory milestones, in particular the filing of an NDA for Pixantrone with the FDA. As discussed above, Defendants would not have been able to receive the cash bonuses for raising capital for the Company without fostering the false impression that the EXTEND SPA was not void as a result of the reduced enrollment in the EXTEND trial. Similarly, Individual Defendants would not have been able to receive individual cash bonuses for the filing of the Pixantrone NDA without fostering the false belief that the EXTEND SPA was not void as a result of the reduced enrollment in the EXTEND trial. If the truth – that the SPA was void and the Company would no longer benefit from it – were known to the investing public, the Company would have been unable to raise the funds detailed above, from which operating capital these bonuses were to be paid. Essentially, the Individual Defendants would only receive the cash awards tied to the filing of the Pixantrone NDA if the Company survived long enough to award them.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

156. In its Form 8-K, filed March 5, 2010, the Company disclosed that on March 1, 2010 the Compensation Committee for CTI approved cash bonuses for 2009 for the Individual Defendants, stating:

> [T]he Compensation Committee determined that the Company had achieved the maximum performance goal established under the program for operating capital raised in 2009 and had achieved the target performance for the tender of its then-outstanding notes due in 2010-2011 in its publicly registered tender offer for those notes. In addition, the Compensation Committee noted that the Company has completed its new drug application submission for pixantrone in 2009. Based on these achievements and its subjective assessment of each named executive officer's individual performance during fiscal year 2009, the Compensation Committee determined to award cash incentives to each of the named executive officers[.]

Defendant J. Bianco received a bonus of $585,000, an amount almost equal to his base salary of $650,000 for 2009. Defendant L. Bianco received a bonus of $204,600, an amount equal to almost two-thirds his base salary of $330,000 for 2009. Defendant Philips received a bonus of $119,000, an amount almost equal to one-third his base salary of $340,000 for 2009. In sum, Individual Defendants received $973,600 in cash as a result of their "achievements," none of which would have been possible had Defendants not maintained the false public impression that the SPA for EXTEND was not voided in March 2008 as a result of the close of enrollment in the trial.

157. Additionally, Individual Defendants held substantial blocks of CTI stock, the value of which, Individual Defendants were aware, would plummet the moment the truth regarding the SPA for EXTEND was revealed. Even though the Individual Defendants were well aware that the SPA ceased to be valid once enrollment in EXTEND was closed at 140 patients, they repeatedly made statements that misrepresented and/or failed to disclose this

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

material fact to the investing public during the Class Period, allowing them to sell off their shares at artificially inflated prices.

158. During the Class Period, the Individual Defendants sold 2,382,465 shares of CTI securities at suspicious times and in suspicious amounts, for which they received $3,259,473 in proceeds, as set forth below:

Defendant	Date of Class Period Sale	Amount of Shares	Avg. Price per share	Total Amount	Shares Owned Post-Transaction	% of Holdings Sold
J. Bianco	9/25/09	318,621	$1.19	$379,733	2,814,739	10.17%
J. Bianco	9/11/09	1,366,108	$1.43	$1,953,534	3,133,360	30.36%
L. Bianco	9/25/09	105,580	$1.23	$129,889	1,417,105	6.93%
Craig Philips	9/25/09	211,500	$1.24	$262,450	2,460,899	7.91%
TOTALS		**2,382,465**		**$3,259,473**		

IX. LOSS CAUSATION

159. As a result of Defendants' materially false and misleading statements and omissions alleged herein, CTI securities traded at artificially inflated prices during the Class Period. Plaintiffs and the other members of the Class purchased or otherwise acquired CTI securities relying upon market information relating to CTI and the integrity of the market price for CTI securities, thus causing economic loss and the damages complained of herein when the truth and/or the effects thereof were revealed and the artificial inflation was removed from the price of CTI's securities.

160. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and other members of the class. But for Defendants' misrepresentation and omissions, which had the effect of overstating Pixantrone's likelihood of receiving FDA approval, Plaintiffs and the other members of the Class would not have purchased CTI's securities at the artificially inflated prices at which they were purchased.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

161. Artificial inflation caused by Defendants' false and misleading statements and omissions is, in part, demonstrated by the following price movements:

DATE	Closing Price the Previous Day	Closing Price After Statement	% Change From Previous Day's Closing Price	Defendants' Statements
2008-03-25	6.4	6.9	7.81%	Press release announcing close of enrollment in EXTEND trial.
2008-11-03	0.31	0.33	6.45%	Press release announcing close of data set for EXTEND trial.
2008-11-11	0.33	0.349	5.76%	Press release announcing achievement of primary efficacy endpoint of EXTEND trial.
2009-01-27	0.0744	0.1145	53.90%	Press release announcing that, based on communication with FDA, Company expects to submit rolling NDA to FDA for Pixantrone.
2009-04-14	0.3075	0.3475	13.01%	Press release announcing submission of rolling NDA to FDA for Pixantrone.
2009-12-05	1.18	1.27	7.63%	Earnings call in which J. Bianco reiterates that EXTEND was awarded an SPA.
2010-2-09	0.64	0.7735	20.86%	Press release defending the Pixantrone NDA; J. Bianco states that the Company believes that many of the key issues the FDA identified were addressed in CTI's own briefing material.

162. On February 8, 2010, the FDA disclosed in its briefing documents to the ODAC that CTI violated the terms of the SPA for the EXTEND study on March 28, 2010, when CTI informed the FDA that it was closing enrollment in the EXTEND trial with 140 patients, less then half the originally agreed upon 320. By the close of the market on Monday February 8, 2010, in response to the devastating revelation that CTI had invalidated the SPA in March 2008,

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

the price of CTI stock had fallen $0.42 per share to close at $0.64 per share – a 39% decline from its previous closing price of $1.06 per share on Friday February 5, 2010, the previous trading day.

163. In response to press and analyst reports regarding the FDA's briefing document and the revelation that the SPA had been invalid since March 28, 2010, Defendants attempted to reassure the market that the Pixantrone NDA still stood a chance of being approved by the FDA, partially through the implication that it would be able to rely on its prior agreements with the FDA regarding the EXTEND study. As a result, the price of CTI's shares climbed slightly.

164. On March 22, 2010, the FDA disclosed additional details at the ODAC meeting regarding CTI's violation of the SPA during the testimony of Dr. Waxman, the FDA's representative. Dr. Waxman revealed that, contrary to CTI's assurances that the decision to close enrollment was based on pre-NDA discussions with the FDA regarding the impact of the reduced enrollment on the EXTEND study, CTI did not seek any formal guidance from the FDA as to the impact that closing the study with only 140 patients would have on the SPA. In reaction to the news, by the close of the market on Monday March 22, 2010, the price of CTI stock fell $0.44 per share to close at $0.47 per share – a 48% decline from its previous closing price of $0.91 per share on Friday March 19, 2010, the previous trading day.

165. The decline in the price of CTI's securities after the truth came to light was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of CTI's securities price declines negate any inference that the loss suffered by Plaintiff and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss suffered by Plaintiffs and the other Class

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

members was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of CTI's securities and the subsequent decline in the value of CTI's securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

166. The foregoing allegations describe Plaintiffs' general theory of injury, demonstrate that Plaintiffs' injury was caused by the scheme to defraud as alleged herein, and negate any inference that Plaintiffs' losses were the result of general market conditions or other factors wholly unrelated to Defendants' false and misleading statements alleged herein. Upon further investigation and expert analysis, Plaintiffs may assert that there were additional inflationary or corrective events that caused or contributed to the damages Plaintiffs incurred.

X. NO SAFE HARBOR

167. The statutory safe harbor provided for forward-looking statements does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made.

168. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

169. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker actually knew that the forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of CTI who knew that the statement was false when made.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

XI. CONTROL PERSON ALLEGATIONS

A. The Individual Defendants are Liable as Direct Participants in the Wrongs Complained of Herein

170. The Individual Defendants are liable as participants in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of CTI's publicly traded securities by disseminating materially false and misleading statements and/or concealing material adverse facts. Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding CTI, their control over, and/or receipt and/or modification of CTI's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning CTI, participated in the fraudulent scheme alleged herein.

171. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of CTI, were privy to confidential, proprietary and material adverse non-public information concerning CTI, its operations, finances, financial condition and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and via reports and other information provided to them in connection therewith.

172. Because of their possession of such information, the Individual Defendants knew or were severely reckless in disregarding that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public. Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading, knew that such statements or documents would be issued or

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

disseminated to the investing public, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

173. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and, through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and publicly disseminated documents alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to either prevent or commit the fraudulent acts alleged herein.

174. The Individual Defendants knew or recklessly disregarded the materially false and misleading nature of the information they caused to be disseminated to the investing public. The Individual Defendants also knew or recklessly disregarded that the failure to disclose the Company's loss of the SPA would cause the Company's public statements and SEC filings to be materially false and misleading, would adversely affect the integrity of the market for the Company's common stock, and would cause the price of the Company's common stock to be artificially inflated. The Individual Defendants acted knowingly or in such reckless manner as to constitute fraud and deceit upon Plaintiffs and the other members of the Class.

B. Individual Defendants, by Reason of Their Status as Senior Executive Officers and/or Directors, are Liable as "Controlling Persons" Within the Meaning of §20(a) of the Exchange Act

175. The Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of §20(a) of the Exchange Act

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of CTI's business.

176. As senior executive officers and as controlling persons of a publicly traded company whose securities were, and are, registered with the SEC pursuant to the Exchange Act, and were traded on the NASDAQ and governed by the federal securities laws, the Defendants had a duty to disseminate promptly accurate and truthful information with respect to CTI's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, to correct any previously issued statements that had become materially misleading or untrue, so the market price of CTI's securities would be based on truthful and accurate information. The Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

COUNT I
For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Against All Defendants

177. Plaintiffs repeat and reallege the foregoing allegations as if fully set forth herein.

178. During the Class Period, Defendants violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 by: (i) employing devices, schemes, and artifices to defraud; (ii) making untrue statements of material fact and/or omitting to state material facts necessary to make the statements not misleading; and (iii) engaging in acts, practices, and a course of business which operated as a fraud and deceit upon the Class. Defendants also failed to disclose material adverse information in connection with their insider sales of CTI securities. Defendants also failed to disclose known risks and uncertainties in CTI's 10-K and 10-Q filings.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

179. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth.

180. The market for CTI securities was open, well-developed and efficient at all relevant times. Defendants' dissemination of materially false and misleading statements and omissions of material facts caused CTI securities to trade at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class were damaged because they acquired CTI securities relying directly or indirectly on Defendants' false and misleading statements and/or omissions, or upon the market's integrity, and would not have purchased or otherwise acquired their CTI securities at the prices they paid, or at all, if they had known that Defendants' misleading statements and omissions artificially inflated market prices, and because when the truth was revealed, CTI's securities price declined dramatically, directly causing the Plaintiffs' and Class members' losses.

181. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

COUNT II
For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

182. Plaintiff repeats and re-alleges the allegations set forth above as if set forth fully herein.

183. The Individual Defendants were and acted as controlling persons of CTI within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in and/or awareness of the Company's operations and/or intimate knowledge of the Company's actual performance, the Individual Defendants had

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

184. In addition, each of the Individual Defendants had direct involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

185. As set forth above, CTI and Individual Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their controlling positions, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Individual Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

COUNT III
For Violations of Sections 10(b) and 20A of the Exchange Act And Rule 10b-5 Against the Individual Defendants for Insider Trading

186. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

187. This claim is asserted pursuant to Section 20A of the Exchange Act against the Individual Defendants by Plaintiffs on behalf of all Class members who purchased shares of

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel: (206) 223-2053
Fax: (206) 343-9636

CTI common stock contemporaneously with the sale of CTI common stock by the Individual Defendants while those defendants were in possession of material, non-public information concerning the EXTEND SPA as alleged herein.

188. The Individual Defendants violated Exchange Act Section 10(b) and Rule 10b-5 by selling shares of CTI's common stock while in possession of material, nonpublic adverse information concerning the status of the EXTEND SPA, which information they each had a duty to disclose, and which they each failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein.

189. Contemporaneously with the Individual Defendants' insider sales of CTI common stock, Plaintiffs and/or other members of the Class purchased shares of CTI securities.

190. The Plaintiffs and/or other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

191. By reason of their violations of the Exchange Act alleged herein, each Individual Defendant is liable to the Plaintiffs and/or other members of the Class who purchased shares of CTI common stock contemporaneously with that Defendant's sales of CTI common stock during the Class Period.

192. The Plaintiff and/or other members of the Class who purchased contemporaneously with the Individual Defendants' CTI securities sales seek disgorgement by the Individual Defendants of profits gained (or losses avoided) from those Individual Defendants' transactions in CTI common stock contemporaneous with the Plaintiffs and/or other members of the Class.

Zwerling, Schachter, & Zwerling, LLP
1904 Third Avenue, Suite 1030
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Tel: (206) 223-2053
Fax: (206) 343-9636

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, pray for relief and judgment, as follows:

(A) declaring this action to be a class action properly maintained pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

(B) awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(C) awarding Plaintiffs and other members of the Class the costs and expenses incurred in this action, including reasonable attorneys' fees, accountants' fees, experts' fees, and other costs and disbursements; and

(D) awarding Plaintiffs and other members of the Class such other and further relief as the Court deems just and proper.

XIII. JURY TRIAL DEMANDED

Plaintiffs hereby demand trial by jury.

DATED this 27th day of September, 2010

ZWERLING, SCHACHTER & ZWERLING, LLP

By: s/ Dan Drachler

Dan Drachler (WSBA #27728)
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Telephone: (206) 223-2053
Facsimile: (206) 343-9636
E-mail: ddrachler@zsz.com

Counsel for the CTIC Investor Group and Liaison Counsel for the Class

BROWER PIVEN
A Professional Corporation
David A.P. Brower
Caitlin M. Moyna
John D.S. Grant
488 Madison Avenue, Eighth Floor
New York, New York 10022
Telephone: (212) 501-9000
Facsimile: (212) 501-0300

BROWER PIVEN
A Professional Corporation
Charles J. Piven
1925 Old Valley Road
Stevenson, Maryland 21153
Telephone: (410) 332-0030
Facsimile: (410) 685-1300

Counsel for the CTIC Investor Group and Lead Counsel for the Class